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DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2021–BT–STD–0005]

RIN 1904–AF09

Energy Conservation Program: Energy Conservation Standards for General Service Lamps

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

ACTION: Final rule.

SUMMARY: In this final rule, the U.S. Department of Energy (''DOE'') is codifying in the Code of Federal Regulations the 45 lumens per watt (''lm/W'') backstop requirement for general service lamps (''GSLs'') that Congress prescribed in the Energy Policy and Conservation Act, as amended. DOE has determined this backstop requirement applies because DOE failed to complete a rulemaking regarding GSLs in accordance with certain statutory criteria. This final rule represents a departure from DOE's previous determination published in 2019 that the backstop requirement was not triggered.

DATES: The effective date of this rule is July 25, 2022.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, 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, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2021-BT-STD-0005.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

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

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, 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) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: *Celia.Sher@hq.doe.gov.*

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I. Introduction

The following section briefly discusses the statutory authority underlying this final rule, as well as some of the relevant historical background related to the statutory backstop requirement.

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes 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 [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include GSLs, the subject of this document. (42 U.S.C. 6295(i)(6))

EPCA directs DOE to conduct two rulemaking cycles to evaluate energy conservation standards for GSLs.[3] (42 U.S.C. 6295(i)(6)(A)–(B)) For the first rulemaking cycle, EPCA directs DOE to initiate a rulemaking process prior to January 1, 2014, to determine whether: (1) To amend energy conservation standards for GSLs and (2) the

[1] All references to EPCA in this document refer to the statute as amended through the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[3] GSLs are defined in EPCA to include GSILs, compact fluorescent lamps (''CFLs''), general service light-emitting diode (''LED'') lamps and organic light emitting diode (''OLED'') lamps, and any other lamps that the Secretary of Energy (Secretary) determines are used to satisfy lighting applications traditionally served by general service incandescent lamps. (42 U.S.C. 6291(30)(BB)(i)) The term ''general service lamp'' does not include any of the 22 lighting applications or bulb shapes explicitly not included in the definition of ''general service incandescent lamp,'' or any general service fluorescent lamp or incandescent reflector lamp. (42 U.S.C. 6291(30)(BB)(ii))

exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(A)(i)) The rulemaking is not limited to incandescent lamp technologies and must include a consideration of a minimum standard of 45 lm/W for GSLs. (42 U.S.C. 6295(i)(6)(A)(ii)) EPCA provides that if the Secretary determines that the standards in effect for general service incandescent lamps (''GSIL'') should be amended, a final rule must be published by January 1, 2017, with a compliance date at least 3 years after the date on which the final rule is published. (42 U.S.C. 6295(i)(6)(A)(iii)) The Secretary must also consider phased-in effective dates after considering certain manufacturer and retailer impacts. (42 U.S.C. 6295(i)(6)(A)(iv)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), or if a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a ''backstop'' under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard. (42 U.S.C. 6295(i)(6)(A)(v))

EPCA further directs DOE to initiate a second rulemaking cycle by January 1, 2020, to determine whether standards in effect for GSILs (which are a subset of GSLs)) should be amended with more stringent maximum wattage requirements than EPCA specifies, and whether the exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(B)(i)) As in the first rulemaking cycle, the scope of the second rulemaking is not limited to incandescent lamp technologies. (42 U.S.C. 6295(i)(6)(B)(ii))

B. March 2016 Notice of Proposed Rulemaking and October 2016 Notice of Proposed Definition and Data Availability

Pursuant to its statutory authority, DOE published a notice of proposed rulemaking (''NOPR'') on March 17, 2016, that addressed the first question that Congress directed it to consider—whether to amend energy conservation standards for GSLs (''March 2016 NOPR''). 81 FR 14528, 14629–14630 (Mar. 17, 2016). In the March 2016 NOPR, DOE stated that it would be unable to undertake any analysis regarding GSILs and other incandescent lamps because of a then-applicable congressional restriction (''the Appropriations Rider''). *See* 81 FR 14528, 14540–14541. The Appropriations Rider prohibited expenditure of funds appropriated by that law to implement or enforce: (1) 10 Code of Federal Regulations (''CFR'') 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps (''IRLs''). Under the Appropriations Rider, DOE was restricted from undertaking the analysis required to address the first question presented by Congress, but was not so limited in addressing the second question—that is, DOE was not prevented from determining whether the exemptions for certain incandescent lamps should be maintained or discontinued. To address that second question, DOE published a Notice of Proposed Definition and Data Availability (''NOPDDA''), which proposed to amend the definitions of GSIL, GSL, and related terms (''October 2016 NOPDDA''). 81 FR 71794, 71815 (Oct. 18, 2016). Notably, the Appropriations Rider, which was originally adopted in 2011 and readopted and extended continuously in multiple subsequent legislative actions, expired on May 5, 2017, when the Consolidated Appropriations Act, 2017 was enacted.[4]

C. January 2017 Final Rules

On January 19, 2017, DOE published two final rules concerning the definitions of GSL, GSIL, and related terms (''January 2017 Definition Final Rules''). 82 FR 7276; 82 FR 7322. The January 2017 Definition Final Rules amended the definitions of GSIL and GSL by bringing certain categories of lamps that had been excluded by statute from the definition of GSIL within the definitions of GSIL and GSL. DOE determined to use two final rules in 2017 to amend the definitions of GSIL and GSLs in order to address the majority of the definition changes in one final rule and the exemption for IRLs in the second final rule. These two rules were issued simultaneously, with the first rule eschewing a determination regarding the existing exemption for IRLs in the definition of GSL and the second rulemaking discontinuing that exemption from the GSL definition. 82 FR 7276, 7312; 82 FR 7322, 7323. As in the October 2016 NOPDDA, DOE stated that the January 2017 Definition Final Rules related only to the second question that Congress directed DOE to consider, regarding whether to maintain or discontinue ''exemptions'' for certain incandescent lamps. 82 FR 7276, 7277; 82 FR 7322, 7324 (*See also* 42 U.S.C. 6295(i)(6)(A)(i)(II)). That is, neither of the two final rules issued on January 19, 2017, established energy conservation standards applicable to GSLs. DOE explained that the Appropriations Rider prevented it from establishing, or even analyzing, standards for GSILs. 82 FR 7276, 7278. Instead, DOE explained that it would either impose standards for GSLs in the future pursuant to its authority to develop GSL standards, or apply the backstop standard prohibiting the sale of lamps not meeting a 45 lm/W efficacy standard. 82 FR 7276, 7277–7278. The two final rules were to become effective as of January 1, 2020.

D. September 2019 Withdrawal Rule and December 2019 Final Determination

On March 17, 2017, the National Electrical Manufacturer's Association (''NEMA'') filed a petition for review of the January 2017 Definition Final Rules in the U.S. Court of Appeals for the Fourth Circuit. *National Electrical Manufacturers Association* v. *United States Department of Energy,* No. 17–1341. NEMA claimed that DOE ''amend[ed] the statutory definition of 'general service lamp' to include lamps that Congress expressly stated were 'not include[d]' in the definition'' and adopted an ''unreasonable and unlawful interpretation of the statutory definition.'' Pet. 2. Prior to merits briefing, the parties reached a settlement agreement under which DOE agreed, in part, to issue a notice of data availability requesting data for GSILs and other incandescent lamps to assist DOE in determining whether standards for GSILs should be amended (the first question of the rulemaking required by 42 U.S.C. 6295(i)(6)(A)(i)).

With the removal of the Appropriations Rider in the Consolidated Appropriations Act, 2017, DOE was no longer restricted from undertaking the analysis and decision-making required to address the first question presented by Congress, *i.e.,* whether to amend energy conservation standards for general service lamps, including GSILs. Thus, on August 15, 2017, DOE published a notice of data availability and request for information (''NODA'') seeking data for GSILs and other incandescent lamps (''August 2017 NODA''). 82 FR 38613.

The purpose of the August 2017 NODA was to assist DOE in determining whether standards for GSILs should be amended. (42 U.S.C. 6295(i)(6)(A)(i)(I)) Comments submitted in response to the August 2017 NODA also led DOE to re-

[4] *See* Consolidated Appropriations Act of 2017 (Pub. L. 115–31, div. D, tit. III); see also Consolidated Appropriations Act, 2018 (Pub. L. 115–141).

consider the decisions it had already made with respect to the second question presented to DOE—whether the exemptions for certain incandescent lamps should be maintained or discontinued. 84 FR 3120, 3122 (*See also* 42 U.S.C. 6295(i)(6)(A)(i)(II)) As a result of the comments received in response to the August 2017 NODA, DOE also re-assessed the legal interpretations underlying certain decisions made in the January 2017 Definition Final Rules. *Id.*

On February 11, 2019, DOE published a NOPR proposing to withdraw the revised definitions of GSL, GSIL, and the new and revised definitions of related terms that were to go into effect on January 1, 2020 (''February 2019 Definition NOPR''). 84 FR 3120. In a final rule published September 5, 2019, DOE finalized the withdrawal of the definitions in the January 2017 Definition Final Rules and maintained the existing regulatory definitions of GSL and GSIL, which are the same as the statutory definitions of those terms (''September 2019 Withdrawal Rule''). 84 FR 46661. The September 2019 Withdrawal Rule revisited the same primary question addressed in the January 2017 Definition Final Rules, namely, the statutory requirement for DOE to determine whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' 42 U.S.C. 6295(i)(6)(A)(i)(II) (*See also* 84 FR 46661, 46667). In the rule, DOE also addressed its interpretation of the statutory backstop at 42 U.S.C. 6295(i)(6)(A)(v) and concluded the backstop had not been triggered. 84 FR 46661, 46663–46664. DOE reasoned that 42 U.S.C. 6295(i)(6)(A)(iii) ''does not establish an absolute obligation on the Secretary to publish a rule by a date certain.'' 84 FR 46661, 46663. ''Rather, the obligation to issue a final rule prescribing standards by a date certain applies if, and only if, the Secretary makes a determination that standards in effect for GSILs need to be amended.'' *Id.* DOE further stated that, since it had not yet made the predicate determination on whether to amend standards for GSILs, the obligation to issue a final rule by a date certain did not yet exist and, as a result, the condition precedent to the potential imposition of the backstop requirement did not yet exist and no backstop requirement had yet been triggered. *Id.* at 84 FR 46664.

Similar to the January 2017 Definition Final Rules, the September 2019 Withdrawal Rule clarified that DOE was not determining whether standards for GSLs, including GSILs, should be amended. DOE stated it would make that determination in a separate rulemaking. *Id.* at 84 FR 46662. DOE initiated that separate rulemaking by publishing a notice of proposed determination (''NOPD'') on September 5, 2019, regarding whether standards for GSILs should be amended (''September 2019 NOPD''). 84 FR 46830. In conducting its analysis for that notice, DOE used the data and comments received in response to the August 2017 NODA and relevant data and comments received in response to the February 2019 Definition NOPR, and DOE tentatively determined that the current standards for GSILS do not need to be amended because more stringent standards are not economically justified. *Id.* at 84 FR 46831. DOE finalized that tentative determination on December 27, 2019 (''December 2019 Final Determination''). 84 FR 71626. DOE also concluded in the December 2019 Final Determination that, because it had made the predicate determination not to amend standards for GSILs, there was no obligation to issue a final rule by January 1, 2017, and, as a result, the backstop requirement had not been triggered. *Id.* at 84 FR 71636.

Two petitions for review were filed in the U.S. Court of Appeals for the Second Circuit challenging the September 2019 Withdrawal Rule. The first petition was filed by 15 States,[5] New York City, and the District of Columbia. See *New York* v. *U.S. Department of Energy,* No. 19–3652 (2d Cir., filed Nov. 4, 2019). The second petition was filed by six organizations[6] that included environmental, consumer, and public housing tenant groups. See *Natural Resources Defense Council* v. *U.S. Department of Energy,* No. 19–3658 (2d Cir., filed Nov. 4, 2019). The petitions were subsequently consolidated. Merits briefing has been concluded, but the case has not been argued or submitted to the Circuit panel for decision. The case has been in abeyance since March 2021, pending further rulemaking by DOE.

Additionally, in two separate petitions also filed in the Second Circuit, groups of petitioners that were essentially identical to those that filed the lawsuit challenging the September 2019 Withdrawal Rule challenged the December 2019 Final Determination. See *Natural Resources Defense Council* v. *U.S. Department of Energy,* No. 20–699 (2d Cir., filed Feb, 25, 2020); *New York* v. *U.S. Department of Energy,* No. 20–743 (2d Cir., filed Feb. 28, 2020). On April 2, 2020, those cases were put into abeyance pending the outcome of the September 2019 Withdrawal Rule petitions.

E. Subsequent Review

On January 20, 2021, President Biden issued Executive Order (''E.O.'') 13990, ''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.'' 86 FR 7037 (Jan. 25, 2021). Section 1 of that Order lists a number of policies related to the protection of public health and the environment, including reducing greenhouse gas emissions and bolstering the Nation's resilience to climate change. *Id.* at 7041. Section 2 of the Order instructs all agencies to review ''existing regulations, orders, guidance documents, policies, and any other similar agency actions promulgated, issued, or adopted between January 20, 2017, and January 20, 2021, that are or may be inconsistent with, or present obstacles to, [these policies].'' *Id.* Agencies are then directed, as appropriate and consistent with applicable law, to consider suspending, revising, or rescinding these agency actions and to immediately commence work to confront the climate crisis. *Id.*

In accordance with E.O. 13990, on May 25, 2021, DOE published a request for information (''RFI'') initiating a re-evaluation of its prior determination that the Secretary was not required to implement the statutory backstop requirement for GSLs (''May 2021 RFI''). 86 FR 28001. DOE solicited information regarding the availability of lamps that would satisfy a minimum efficacy standard of 45 lm/W, as well other information that may be relevant to a possible implementation of the statutory backstop. *Id.* On December 13, 2021, DOE published a NOPR proposing to codify in the CFR the 45 lm/W backstop requirement for GSLs and welcomed comments on the proposal (''December 2021 NOPR''). 86 FR 70755.

DOE received comments in response to the December 2021 NOPR from the interested parties listed in Table I.1.

[5] The petitioning States are the States of New York, California, Colorado, Connecticut, Illinois, Maryland, Maine, Michigan, Minnesota, New Jersey, Nevada, Oregon, Vermont, and Washington and the Commonwealth of Massachusetts.

[6] The petitioning organizations are the Natural Resource Defense Council, Sierra Club, Consumer Federation of America, Massachusetts Union of Public Housing Tenants, Environment America, and U.S. Public Interest Research Group.

TABLE I.1—WRITTEN COMMENTS RECEIVED IN RESPONSE TO THE DECEMBER 2021 NOPR

Commenter(s)	Abbreviation	Commenter type
American Lighting Association	ALA	Trade Association.
Amy Glass	Glass	Individual commenter.
Anonymous	Anonymous	Individual commenter.
Anonymous	Anonymous	Individual commenter.
Anonymous	Anonymous	Individual commenter.
Anonymous	Anonymous	Individual commenter.
Anonymous	Anonymous	Individual commenter.
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Alliance of Nurses for Healthy Environments, Alliance to Save Energy, The California Efficiency + Demand Management Council, Center for Biological Diversity, Climate Smart Missoula, Colorado Energy Office, Consumer Federation of America, E4TheFuture, Energy Efficiency Alliance of New Jersey, Campaign for 100% Renewable Energy, Environment America, Evergreen Action, Green Energy Consumers Alliance, Interfaith Power & Light, Maine Department of Environmental Protection, Montana Environmental Information Center, National Consumer Law Center, Northeast Energy Efficiency Partnership, Nevada Governor's Office of Energy, Nevada Legislature, New Buildings Institute, Northwest Energy Coalition, Carbon-Free Buildings RMI, Southwest Energy Efficiency Project (''SWEEP''), Urban Green Council, Utah Clean Energy, Vermont Energy Investment Corporation, Washington Department of Commerce.	ASAP et al	Energy Efficiency Organization; State Official/Agency.
Attorneys General of New York, California, Colorado, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Vermont, Washington, The Commonwealth of Massachusetts, The District of Columbia, and The City of New York.	Attorneys General	State Official/Agency.
California Energy Commission	CEC	State Official/Agency.
Pacific Gas and Electric Company, San Diego Gas & Electric Company, Southern California Edison.	CA IOUs	Utilities.
Center for Energy and Environment Competitive Enterprise Institute, Regulatory Action Center FreedomWorks Foundation, JunkScience.com, Project 21, Center for Energy & Environmental Policy Caesar Rodney Institute, Rio Grande Foundation, The Cornwall Alliance for the Stewardship of Creation, Americans for Limited Government, Institute for Energy Research, National Center for Public Policy Research, Roughrider Policy Center, 60 Plus Association, Independent Women's Forum, Committee for a Constructive Tomorrow, Independent Women's Voice.	Free Market Organizations	Consumer Advocacy Organizations.
Consumer Federation of America, The National Consumer Law Center	CFA and NCLC	Consumer Advocacy Organizations.
David Maier	Maier	Individual commenter.
David Walton	Walton	Individual commenter.
Edison Electric Institute	EEI	Utilities.
GE Lighting, a Savant Company	GE Lighting	Manufacturer.
Institute for Policy Integrity (''IPI'') at NYU School of Law, Montana Environmental Information Center, Natural Resources Defense Council, Sierra Club, Union of Concerned Scientists.	IPI et al	Energy Efficiency Organizations.
Jean Sherman	Sherman	Individual commenter.
Lutron Electronics Co., Inc	Lutron	Manufacturer.
Minimise USA	Minimise USA	Energy Efficiency Services Company.
National Association of State Energy Officials	NASEO	State Official/Agency.
National Electrical Manufacturers Association	NEMA	Trade Association.
National Retail Federation, Retail Industry Leaders Association	NRF and RILA	Trade Association.
New York State Energy Research and Development Authority	NYSERDA	State Official/Agency.
Northwest Energy Efficiency Alliance	NEEA	Energy Efficiency Organization.
Northwest Power and Conservation Council	NPC Council	State Organization.
Project 21—National Research for Public Policy Research	Project 21	Research Organization.
Sierra Club, National Resources Defense Council, Earthjustice	SC, NRDC, and EJ	Energy Efficiency Organizations.
VALU Home Centers	VALU Home Centers	Retailer.
William Hough	Hough	Individual commenter.

The comments received on the December 2021 NOPR are summarized and addressed in the following section. A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[7]

[7] The parenthetical reference provides a reference for information located in the docket of DOE's re-evaluation of the statutory backstop for GSLs. (Docket No. EERE–2021–BT–STD–0005, which is maintained at *www.regulations.gov*). The references are arranged as follows: (Commenter name, comment docket ID number at page of that document).

II. Final Rule

In this final rule, DOE has determined that the 45 lm/W backstop requirement for GSLs at 42 U.S.C. 6295(i)(6)(A)(v) has been triggered because of DOE's failure to complete the first phase of

rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), and because the final rules that DOE published did not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W. As a result of this failure to complete certain rulemakings, EPCA dictates that DOE prohibit sales of GSLs that do not meet a minimum 45 lm/W standard. (42 U.S.C. 6295(i)(6)(A)(v))

A. Statutory Backstop Requirement

As described in section I.A of this document, EPCA specifies several criteria that DOE must adhere to in its first rulemaking cycle for GSLs. (*See* 42 U.S.C. 6295(i)(6)(A)(i)–(iv)) If DOE fails to complete a rulemaking in accordance with clauses (i) through (iv) of 42 U.S.C. 6295(i)(6)(A) or if the final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, clause (v) requires DOE to prohibit sales of lamps with an efficacy below 45 lm/W ''effective beginning January 1, 2020.''

1. Prior Consideration of the Backstop Requirement

a. Prior to the September 2019 Withdrawal Rule

In the March 2016 NOPR proposing energy conservation standards for GSLs, DOE explicitly addressed the backstop provision at 42 U.S.C. 6295(i)(6)(A)(v). 81 FR 14528 (March 17, 2016). Specifically, DOE stated that due to the Appropriations Rider, DOE was unable to perform the analysis required in clause (i) of 42 U.S.C. 6295(i)(6)(A) and as a result, the backstop in 42 U.S.C. 6295(i)(6)(A)(v) is automatically triggered. 81 FR 14528, 14540. DOE reiterated that it was not considering GSILs, including exclusions or exemptions, in the rulemaking due to the Appropriations Rider. 81 FR 14528, 14582. DOE further explained that under 42 U.S.C. 6295(i)(6)(A)(v), if it failed to (1) complete a rulemaking in accordance with clauses (i) through (iv), which included determining whether the exemptions for certain incandescent lamps should be maintained or discontinued, or (2) publish a final rule that would meet or exceed the energy savings associated with the statutory 45 lm/W requirement, then the backstop would be triggered beginning January 1, 2020. *Id.* Thus, in the March 2016 NOPR, DOE assumed that the backstop would be triggered beginning January 1, 2020. *Id.* Further, DOE stated that lamps that meet the proposed GSL definition would be subject to the 45 lm/W efficacy level and estimated an associated energy savings of approximately 3 quadrillion Btu (''quads'') for lamps sold in 2020–2049 and a carbon reduction of approximately 200 million metric tons by 2030. 81 FR 14528, 14534.

In the January 2017 Definition Final Rules, DOE did not interpret paragraph (6)(A) as requiring DOE to establish amended standards for GSLs. 82 FR 7276, 7283. DOE stated that clause (v) expressly contemplates the possibility that DOE would not finalize a rule that develops alternative standards for GSLs. *Id.* In these rules, DOE did not make any determination regarding standards for GSLs. 82 FR 7278, 7316. DOE acknowledged that the backstop would go into effect if DOE failed to complete the rulemaking as prescribed by EPCA by January 1, 2017, or the final rule did not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W. *Id.* While not explicitly stating its assumption that the backstop requirement would be triggered, DOE set a January 1, 2020, effective date for the definitions rule, which coincided with the effective date of the statutory backstop requirement. DOE also noted its commitment to working with manufacturers to ensure a successful transition if the backstop standard went into effect. To that end, on January 18, 2017, DOE issued a ''Statement Regarding Enforcement of 45 LPW General Service Lamp Standard'' (''January 2017 Enforcement Statement'') stating that EPCA requires that, effective beginning January 1, 2020, DOE shall prohibit the sale of any GSL that does not meet a minimum efficacy standard of 45 lm/W.[8] In the enforcement statement, DOE advised that it could issue a policy that provides additional time allowing for the necessary flexibility for manufacturers to comply with the 45 lm/W standard. *Id.*

b. September 2019 Withdrawal Rule and the December 2019 Final Determination

In the September 2019 Withdrawal Rule, DOE concluded that the backstop requirement had not been triggered. 84 FR 46661, 46664. DOE stated that it initiated the first GSL standards rulemaking process by publishing a notice of availability of a framework document in December 2013, satisfying the requirements in 42 U.S.C. 6295(i)(6)(A)(i) to initiate a rulemaking by January 1, 2014. 84 46661, 46663. DOE further stated its belief that Congress intended for the Secretary to make a predicate determination about GSILs, and that the obligation to issue a final rule prescribing standards by a date certain applies if, and only if, the Secretary makes a determination that standards in effect for GSILs need to be amended. 84 FR 46661, 46663–46664. Since DOE had not yet made the predicate determination on whether to amend standards for GSILs, DOE found the obligation to issue a final rule by a date certain did not yet exist and, as a result, the condition precedent to the potential imposition of the backstop requirement did not yet exist and no backstop requirement had yet been triggered. *Id.*

In the December 2019 Final Determination, DOE reiterated its interpretation that the statutory deadline for the Secretary to complete a rulemaking for GSILs in 42 U.S.C. 6295(i)(6)(A)(iii) does not establish an absolute obligation on the Secretary to publish a rule by a date certain. 84 FR 71626, 71635. Instead, DOE stated that this deadline applies only if the Secretary makes a determination that standards for GSILs should be amended. *Id.* at 84 FR 71636. Otherwise, DOE again stated, it could result in a situation where a prohibition is automatically triggered for a category of lamps for which no new standards, much less prohibition, are necessary. *Id.* In the December 2019 Final Determination, since DOE made what it characterized as the predicate determination that standards for GSILs do not need to be amended, DOE found that the obligation to issue a final rule by a date certain did not exist and, as a result, the condition precedent to the potential imposition of the backstop requirement did not exist and no backstop requirement had been triggered. *Id.*

2. Proposed Determination Regarding Operation of the Backstop Requirement

As presented in the December 2021 NOPR, Congress identified two circumstances that would trigger application of the backstop requirement: (1) If DOE ''fails to complete a rulemaking in accordance with clauses (i) through (iv)'' of section 6295(i)(6)(A); or (2) ''if the final rule'' promulgated under this rulemaking ''does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lumens per watt.'' 86 FR 70755, 70760; 42 U.S.C. 6295(i)(6)(A)(v). In the December 2021 NOPR, DOE tentatively determined that the backstop requirement has been triggered because both of the foregoing circumstances have occurred. *Id.*

[8] Available at *www.energy.gov/sites/default/files/2017/01/f34/Statement%20on%20Enforcement%20of%20GSL%20Standard%20-%201.18.2017.pdf.*

DOE explained in the December 2021 NOPR that it failed to complete the first cycle of rulemaking in accordance with clauses (i) through (iv) of 42 U.S.C. 6295(i)(6)(A) for at least two reasons. *Id.* The first reason is that DOE failed to complete this first GSL rulemaking in a timely manner. The structure of section 6295(i)(6)(A) reflects an expectation by Congress that by January 1, 2017, the outcome of DOE's GSL rulemaking would have been known, and, if either amended standards or the backstop were to be applicable, those would be in place no later than January 1, 2020. *Id.*

DOE also stated in the December 2021 NOPR, that the position it advanced in the September 2019 Withdrawal Rule and the December 2019 Final Determination—namely, that the backstop provision is premised on the Secretary first making a determination that standards for GSILs should be amended and that the statute does not impose a deadline for the GSIL determination—fails to give meaning to all of the surrounding statutory text, as DOE is obligated to do. *See* 84 FR 46661, 46663–46664; 84 FR 71626, 71635; *see* also 42 U.S.C. 6295(i)(6)(A)(iii). DOE stated that in looking at the surrounding context of sections 6295(i)(6)(A) and 6295(i)(6)(B), it is clear that Congress intended DOE's first GSL rulemaking to be completed by January 1, 2017—primarily due to Congress providing interested parties a gap of time between the conclusion of this rulemaking and the deadline for compliance, thus giving interested parties time to adjust to any changes. *Id.*

DOE explained in the December 2021 NOPR that in section 6295(i)(6)(A), Congress explicitly contemplated two possible outcomes: (1) A final rule amending standards for GSLs, or (2) imposition of the backstop of 45 lm/W. Under the first scenario, DOE would have been obligated to publish a final rule by January 1, 2017, with an effective date no earlier than three years after publication—thereby giving manufacturers a three-year lead time to prepare for the changed standards. *See* 42 U.S.C. 6295(i)(6)(A)(iii). Under the second scenario, the backstop would come into effect, but not until January 1, 2020—giving manufacturers the same three-year lead time to adjust to the forthcoming efficacy standard of 45 lm/W. *See Id.* at 42 U.S.C. 6295(i)(6)(A)(v). 86 FR 70755, 70760–61.

DOE further stated in the December 2021 NOPR that even if the statute contemplated a third possible scenario—a determination by DOE that standards for GSLs need not be amended under which the backstop was not triggered—it is clear from section 6295(i)(6)(A) that Congress expected this determination would be made no later than January 1, 2017. 86 FR 70755, 70761.

DOE also made the case in the December 2021 NOPR that this allowance for lead time is reflected in the preemption exception provision in section 6295(i)(6)(A)(vi), which gives California and Nevada the authority to adopt, with an effective date beginning January 1, 2018 or after, either:

(1) A final rule adopted by the Secretary in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv);

(2) If a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), the backstop requirement under 42 U.S.C. 6295(i)(6)(A)(v); or

(3) In the case of California, if a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), any California regulations related to ''these covered products'' adopted pursuant to state statute in effect as of the date of enactment of the Energy Independence and Security Act of 2007.

This provision allows California and Nevada to implement either a final DOE rule amending standards for GSLs or the 45 lm/W backstop standard on January 1, 2018, two years earlier than the rest of the country. This provision thus assumes that California and Nevada would have to have known whether DOE had completed a final rule amending standards for GSLs by January 1, 2017, so that manufacturers subject to standards in those states would have a practicable one-year lead time to comply. *Id.*

Lastly, DOE stated in the December 2021 NOPR that Congress' mandate in 42 U.S.C. 6295(i)(6)(B) that DOE initiate the second cycle of rulemaking by January 1, 2020, coincides with a schedule in which standards are adopted (or the backstop is implicated by January 1, 2017, with a minimum three-year lead time. *Id.*

DOE also tentatively determined in the December 2021 NOPR that in addition to failing to complete the first cycle of rulemaking timely, the second reason why DOE's rulemaking was not ''in accordance with clauses (i) through (iv)'' of section 6295(i)(6)(A) is because DOE's rulemaking did not ''consider[ ] a minimum standard of 45 lumens per watt for general service lamps'' as required under 42 U.S.C. 6295(i)(6)(A)(ii)(II). 86 FR 70761. DOE considered GSILs only in the scope of the December 2019 Final Determination analysis, with lamps having a maximum efficacy less than 45 lumens per watt. *Id.* While DOE did not analyze lamps other than GSILs in the scope of the December 2019 Final Determination analysis, DOE did look at the impact on GSIL shipments as a result of consumers choosing to purchase other lamps, such as compact fluorescent lamps (''CFLs'') and light-emitting diode (''LED'') lamps, if standards for GSILs were amended as discussed in section VI.A of the December 2019 Final Determination. Therefore, DOE preliminarily concluded in the December 2021 NOPR that it could not have considered a 45 lumens per watt standard level as part of that rulemaking determination because of the GSIL limited scope. *Id.*

DOE explained in the December 2021 NOPR that although DOE's failure to ''complete a rulemaking in accordance with clauses (i) through (iv)'' is itself sufficient to trigger application of the backstop, DOE also did not determine whether its final rule (or rules) in this first cycle of rulemaking produced savings that are ''greater than or equal to the savings from a minimum efficacy standard of 45 lm/W[.]'' 42 U.S.C. 6295(i)(6)(A)(v). That is an independent basis for application of the backstop under section 6295(i)(6)(v). Congress provided that the backstop would be triggered ''if the final rule does not produce energy savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W.'' *Id.* Since DOE did not compare whether any energy savings resulting from either the September 2019 Withdrawal Rule or the December 2019 Final Determination would produce energy savings that are greater than or equal to a minimum efficacy standard of 45 lm/W, DOE preliminary determined in the December 2021 NOPR that the backstop requirement in section 6295(1)(6)(A)(v) was triggered.[9] *Id.*

For the foregoing reasons, DOE determines that the backstop requirement in 42 U.S.C. 6295(i)(6)(A)(v) was triggered and should have been effective as of January 1, 2020 because DOE failed to complete a GSL rulemaking in accordance with certain statutory criteria.

[9] Although DOE did perform various energy savings analyses in the December 2019 Final Determination, it was not the comparison to a 45 lumens per watt efficacy standard required by 42 U.S.C. 6295(i)(6)(A)(v). *See, e.g.,* 84 FR 71632 (''The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards. In this case, the standards case represents energy savings not from the technology outlined in a [trial standard level], but from product substitution as consumers are priced out of the market for GSILs.'').

3. Discussion of Comments and Final Determination Regarding Operation of the Backstop

In response to the December 2021 NOPR, NEMA encouraged DOE to review its past comments regarding implementation of the backstop. (NEMA, No. 51 at p. 2) DOE notes that in the September 2019 Withdrawal Rule proceeding, NEMA commented that the backstop standard had not be triggered because the Secretary had not determined whether to amend GSIL standards under 42 U.S.C. 6295(i)(6)(A)(iii). In that proceeding, NEMA also commented that the backstop standard is not self-executing and requires the Secretary to issue a prohibitory order. NEMA asserted that the Secretary had not issued such an order because the Secretary had not failed to complete a rulemaking in accordance with clauses (i) through (iv) or that such final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W because the obligation to issue such a rule did not yet exist. 84 FR 46661, 46663.

Further, in response to the December 2021 NOPR, the Free Market Organizations stated opposition to DOE's proposed implementation of the 45 lm/W backstop because it bypasses consumer protections in EPCA and adversely impacts product cost, choice, and features. (Free Market Organizations, No. 65 at p. 2) They asserted that if Congress wanted the 45 lm/W backstop to be applicable to all GSILs as of January 1, 2020, it could have stated so clearly and succinctly, as EPCA is replete with such statutorily-imposed minimum efficiency standards for home appliances that automatically take effect on the date specified. The Free Market Organizations asserted that in the case of GSLs, the statute delineates agency actions that are preconditions to any triggering of the 45 lm/W backstop requirement, namely that DOE determine that existing standards need to be amended and then either fails to amend the standards or sets a standard weaker than would have been achieved by the backstop. The Free Market Organizations asserted that DOE never made the threshold determination and thus the 45 lm/W backstop does not apply. (Free Market Organizations, No. 65 at p. 3)

DOE received comments from the Attorneys General, NPC Council, ASAP et al., and SC, NRDC, and EJ in support of DOE's tentative conclusion in the December 2021 NOPR that the backstop had been triggered. (Attorneys General, No. 60 at p. 2; NPC Council, No. 46 at p. 2; ASAP et al., No. 63 at p. 2; SC, NRDC, and EJ, No. 58 at pp. 1–2) In particular, SC, NRDC, and EJ commented that the defects pointed out by DOE in the December 2021 NOPR are not the only bases for concluding that DOE has failed to complete a rulemaking in accordance with clauses (i) through (iv) of 42 U.S.C. 6295(i)(6)(A). Rather, SC, NRDC, and EJ commented that DOE has failed to meet not just two, but all four of the rulemaking criteria prescribed in 42 U.S.C. 6295(i)(6)(A). Moreover, these commenters asserted that DOE triggered the backstop more than eight years ago when it failed to meet the January 1, 2014 statutory deadline to initiate the required rulemaking procedure. (SC, NRDC, and EJ, No. 58 at pp. 1–2) Additionally, IPI et al. commented that the statutory backstop provision in 42 U.S.C. 6295(i)(6)(A)(v) is absolute and unambiguous, suggesting that it applies even if it did not meet EPCA's typical mandate that standards be ''economically justified,'' or that ''the benefits of the standards exceed its burdens.'' These commenters stated that federal law demands that DOE promulgate the backstop standard regardless of the magnitude of climate benefits or the results of its cost-benefit analysis more broadly. (IPI et al., No. 54 at pp. 4–5)

DOE concludes that the 45 lm/W backstop requirement has been triggered for the reasons put forth in the December 2021 NOPR. That is, DOE failed to complete the first cycle of rulemaking in accordance with clauses (i) through (iv) of 42 U.S.C. 6295(i)(6)(A), and DOE's final rules that were published did not produce savings that are ''greater than or equal to the savings from a minimum efficacy standard of 45 lm/W[.]'' 42 U.S.C. 6295(i)(6)(A)(v).

First as explained above and in the December 2021 NOPR, DOE did not complete the first cycle rulemaking in accordance with the criteria established by EPCA because it did not complete the rulemaking in a timely manner. (42 U.S.C. 6295(i)(a)(6)(i)–(iv)) As discussed, the structure of section 6295(i)(6)(A) reflects an expectation by Congress that by January 1, 2017, the outcome of DOE's GSL rulemaking would have been known, and, if either amended standards or the backstop were to be applicable, those would be in place no later than January 1, 2020. Even if the statute contemplated a third possible scenario as previously suggested by commenters—*i.e.,* a determination by DOE that standards for GSLs need not be amended, in which circumstance the backstop would not be triggered (see *e.g.,* NEMA, Docket No. EERE–2018–BT–STD–0010,[10] No. 329 at p. 40) —it is clear from section 6295(i)(6)(A) that Congress expected this determination would be made no later than January 1, 2017. This lack of a timely concluded rulemaking by itself constitutes a failure to complete a rulemaking in accordance with the enumerated clauses, thereby triggering the backstop.

While failure to satisfy any one of the specified criterion alone triggers the backstop, DOE agrees with those commenters stating that DOE also failed to conduct the evaluation required by 42 U.S.C. 6295(i)(6)(A)(ii)(II)—*i.e.,* an evaluation of a 45 lm/W standard for GSLs. As explained, the December 2019 Final Determination only evaluated standards in relation to a 45 lm/W requirement for GSILs. By providing only a limited evaluation of a 45 lm/W requirement and by excluding other GSLs from this evaluation (*e.g.,* CFLs, LEDs), DOE failed to consider a minimum standard of 45 lm/W for GSLs as required by 42 U.S.C. 6295(i)(6)(A)(ii)(II).

In addition, Congress provided that the backstop requirement is triggered if the rulemaking completed under 42 U.S.C. 6295(i)(6)(A) ''does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 [l/w].'' 42 U.S.C. 6295(i)(6)(A)(v). That is an independent basis for application of the backstop under section 6295(i)(6)(v). As discussed, neither the September 2019 Withdrawal Rule nor the December 2019 Final Determination considered whether any energy savings resulting from either rule would produce energy savings that are greater than or equal to a minimum efficacy standard of 45 lm/W.

For the foregoing reasons, DOE has determined the backstop requirement in 42 U.S.C. 6295(i)(6)(A)(v) was triggered and should have been effective as of January 1, 2020.

DOE received extensive comments from IPI et al. regarding consideration of greenhouse gas emission and the estimated value of emission reductions as a result of the backstop requirement. (*See generally* IPI *et al.,* No. 54) DOE agrees with IPI et al. that once triggered, application of the backstop requirement does not necessitate a determination of economic justification. (*See* IPI et al., No. 54 at pp. 4–5) Importantly, the 45 lm/W backstop standard is explicitly commanded by Congress in 42 U.S.C. 6295(i)(6)(A)(v). This is not a

[10] Available at: *www.regulations.gov/docket/EERE-2018-BT-STD-0010.*

discretionary rulemaking standard subject to evaluation of the factors at 42 U.S.C. 6295(o). However, consistent with Executive Order 12866, DOE notes that it has provided a cost-benefit analysis of implementing the 45 lm/W backstop for GSLs, which is discussed in greater detail for the public in section IV.A of this document.

DOE received a number of comments that objected to the 45 lm/W requirement generally. DOE received comments stating that regulation was not necessary as market forces were shifting lighting technology to LED lamps. DOE also received comments stating that the backstop standard would be costly to consumers and remove consumer choice in product and product features. Commentators also stated potential health and safety concerns resulting from the implementation of the backstop requirement. These comments are discussed in detail in section II.D of this document.

DOE also received comments in general support of the 45 lm/W requirement. NPC Council stated that having a consistent federal standard in place will enable better energy efficiency planning and a more equitable distribution of the benefits to consumers. (NPC Council, No. 46 at p. 2) NYSERDA, CFA and NCLC, NRF and RILA, ALA, Lutron, NEEA, CEC, CA IOUs, SC, NRDC, and EJ, ASAP *et al.,* the Attorneys General, and IPI et al. stated that the nation would experience benefits such as reduced electricity bills and reduced climate emissions from the implementation of the 45 lm/W backstop requirement. (NYSERDA, No. 48 at pp. 1–2; CFA and NCLC, No. 52 at p. 2; NRF and RILA, No. 55 at p. 2; ALA, No. 57 at p. 1; Lutron, No. 62 at p. 2; NEEA, No. 64 at pp. 1–2; CEC, No. 53 at p. 1; SC, NRDC, and EJ, No. 58 at p. 1; ASAP et al., No. 63 at p. 1; Attorneys General, No. 60 at p. 1; IPI et al., No. 54 at p. 4) ALA stated its support for the adoption of the 45 lm/W backstop requirement with the caveat that it opposed a 60-day effective date for the backstop. ALA also noted that its comments are submitted in support of the NEMA positions. (ALA, No. 57 at p. 2)

As stated, DOE has determined that it failed to conduct a rulemaking (or rulemakings) in accordance with the criteria specified by EPCA at 42 U.S.C. 6295(i)(6)(A)(i)–(iv) and the final rules that were published did not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W. (42 U.S.C. 6295(i)(6)(A)(v)) Accordingly, the statute requires the Secretary to prohibit the sale of any GSL that does not meet a minimum efficacy standard of 45 lm/W.

B. Scope of Backstop Requirement

Once triggered, the backstop requirement as specified in 42 U.S.C. 6295(i)(6)(A)(v) directs DOE to prohibit the sale of GSLs that do not meet a minimum efficacy standard of 45 lm/W. DOE's previous regulatory definition of GSL did not include any of the 22 lighting applications or bulb shapes explicitly not included in the definition of GSIL,[11] or any general service fluorescent lamp or IRL. (*See,* 42 U.S.C. 6291(30)(BB)(ii))

On August 21, 2021, DOE published a notice of proposed rulemaking proposing to amend the then-current definitions of GSL and GSIL to be defined as previously set forth in the January 2017 Final Rules. 86 FR 46611 (''August 2021 Definition NOPR''). DOE issued a final rule published elsewhere in this issue of the **Federal Register** responding to comments received on the August 2021 Definition NOPR and adopting the definitions of GSL and GSIL as set forth in that NOPR. These definitions of GSL and GSIL adopted by DOE in the 2022 Definition Final Rule are as follows:

General service lamp means a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or at 277 volts for integrated lamps, or is able to operate at any voltage for non-integrated lamps; has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps do not include:

(1) Appliance lamps;
(2) Black light lamps;
(3) Bug lamps;
(4) Colored lamps;
(5) G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002;
(6) General service fluorescent lamps;
(7) High intensity discharge lamps;
(8) Infrared lamps;
(9) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases;
(10) Lamps that have a wedge base or prefocus base;
(11) Left-hand thread lamps;
(12) Marine lamps;
(13) Marine signal service lamps;
(14) Mine service lamps;
(15) MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002, operate at 12 volts, and have a lumen output greater than or equal to 800;
(16) Other fluorescent lamps;
(17) Plant light lamps;
(18) R20 short lamps;
(19) Reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;
(20) S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002;
(21) Sign service lamps;
(22) Silver bowl lamps;
(23) Showcase lamps;
(24) Specialty MR lamps;
(25) T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002, nominal overall length less than 12 inches, and that are not compact fluorescent lamps;
(26) Traffic signal lamps.

General service incandescent lamp means a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however, this definition does not apply to the following incandescent lamps—
(1) An appliance lamp;
(2) A black light lamp;
(3) A bug lamp;

[11] As defined in EPCA ''general service incandescent lamp'' does not include the following incandescent lamps: (I) An appliance lamp; (II) A black light lamp; (III) A bug lamp; (IV) A colored lamp; (V) An infrared lamp; (VI) A left-hand thread lamp; (VII) A marine lamp; (VIII) A marine signal service lamp; (IX) A mine service lamp; (X) A plant light lamp; (XI) A reflector lamp; (XII) A rough service lamp; (XIII) A shatter-resistant lamp (including a shatter-proof lamp and a shatter-protected lamp); (XIV) A sign service lamp; (XV) A silver bowl lamp; (XVI) A showcase lamp; (XVII) A 3-way incandescent lamp; (XVIII) A traffic signal lamp; (XIX) A vibration service lamp; (XX) A G shape lamp (as defined in ANSI C78.20–2003 and C79.1–2002 with a diameter of 5 inches or more; (XXI) A T shape lamp (as defined in ANSI C78.20–2003 and C79.1–2002) and that uses not more than 40 watts or has a length of more than 10 inches; (XXII) A B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp (as defined in ANSI C79.1–2002 and ANSI C78.20–2003) of 40 watts or less. (42 U.S.C. 6291(30)(D)(ii))

(4) A colored lamp;
(5) A G shape lamp with a diameter of 5 inches or more as defined in ANSI C79.1–2002;
(6) An infrared lamp;
(7) A left-hand thread lamp;
(8) A marine lamp;
(9) A marine signal service lamp;
(10) A mine service lamp;
(11) A plant light lamp;
(12) An R20 short lamp;
(13) A sign service lamp;
(14) A silver bowl lamp;
(15) A showcase lamp; and
(16) A traffic signal lamp.

NYSERDA submitted comments encouraging DOE to publish final rules for both the 45 lm/W backstop and expanded scope definitions as these rules will provide overdue savings. (NYSERDA, No. 48 at p. 3) CEC, CA IOUs, SC, NRDC, and EJ, CFA, NCLC, the Attorneys General, and NYSERDA stated that DOE should promptly reinstate the January 2017 Definition Final Rules expanding the definitions of GSL and GSIL to take effect no later than the effective date of the GSL backstop, thus enforcing the backstop sales prohibition on the expanded scope of GSLs. (CA IOUs, No. 56 at pp. 2–3; SC, NRDC, and EJ, No. 58 at p. 3; CFA, NCLC, No. 52 at p. 1; Attorneys General, No. 60 at p. 1) CEC stated that reinstatement of the expanded definition of GSLs finalized in the January 2017 Definition Final Rules would achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (CEC, No. 53 at pp. 4–5) The CA IOUs and NYSERDA commented that reinstatement of the January 2017 Definition Final Rules was identified for review in President Biden's Executive Order 13990 and slated for completion by December 31, 2021, and that additional delay to finalize both rules prevents realizing the full energy savings potential of the GSL backstop standard. (CA IOUs, No. 56 at p. 2; NYSERDA, No. 48 at p. 2) The CA IOUs stated that California and several other states have adopted and implemented the 45 lm/W backstop standard including DOE's expanded GSL definition. The CA IOUs further stated that in California the CEC have reported no consumer complaints about product availability. (CA IOUs, No. 56 at p. 3) The Attorneys General stated that together, prompt enforcement of the backstop standard and the expanded definition of GSLs will significantly increase GSL efficiency and ensure that consumers, businesses, and governments enjoy the full economic and environmental benefits of strong national energy efficiency standards. (Attorneys General, No. 60 at p. 3) Minimise USA stated that it supports setting a minimum efficacy standard of 45 lm/W for GSLs and GSILs, such as those used in decorative, recessed, and track lighting fixtures. (Minimise USA, No. 38 at p.1)

As noted, the 2022 Definition Final Rule amended the definitions of GSL and GSIL as they were specified in the January 2017 Definition Final Rules. For the current definition of GSL adopted in the 2022 Definition Final Rule, DOE adopted additional detail to the statutory definition by specifying the base type, lumens, and voltages of GSLs. DOE also removed the GSIL exemptions for certain incandescent lamps that are used in general lighting applications and included those lamps in the definition of GSIL and GSL. The adopted definitions of GSL and GSIL explicitly include not only A-shaped or pear-shaped light bulbs but also the smaller, decorative shaped light bulbs resembling a candle, bullet or globe and often used in chandeliers, desk lamps, ornamental wall lights, etc. Additionally, the definitions include reflector shaped light bulbs that have a cone-like shape with an inner reflective coating that directs light and are often used in recessed light fixtures (*e.g.,* lights within the ceiling wall). Based on estimates from DOE's 2015 Lighting Market Characterization Report, the GSL definition adopted in the 2022 Definitions Final Rule comprise 5.8 billion lamps. The sales prohibition under the backstop requirement would affect any lamp type that is defined as a GSL.

C. Implementation and Enforcement

In the December 2021 NOPR, DOE stated that once triggered, the backstop requirement provides that DOE ''shall prohibit'' sales of any GSL below the 45 lm/W backstop standard ''effective beginning January 1, 2020.'' 86 FR 70755, 70766. DOE noted in its prior explanation that if it is determined that the backstop is triggered, DOE would not have discretion regarding the effective date of the backstop standard. *Id.* DOE also recognized the unique circumstances created by the delay in correctly addressing the applicability of the backstop. *Id.* DOE stated that were it to issue a final determination that the backstop has been triggered, DOE proposes to use its enforcement discretion to provide the necessary flexibility to avoid undue market disruption. *Id.* DOE presented an example of a discretionary enforcement approach, in which DOE would consider a staggered implementation that weighs factors such as the point of manufacture, the point of sale, and the anticipated inventory of different lamp categories. *Id.* DOE stated that this flexible enforcement approach takes into account the disruptive supply chain effects of stranded inventory and the significant consumer and environmental benefits of full compliance, and would best balance Congress's intent to facilitate a smooth transition with Congress's intent that the different efficacy standards were to be in place as of January 1, 2020. *Id.* DOE requested input of this consideration and on additional considerations for enforcement. *Id.*

Several commenters addressed whether DOE has discretion in enforcing the 45 lm/W backstop standard. NEMA asserted that DOE acknowledged in the December 2021 NOPR that it has the discretion to set an effective date that recognizes the need for an appropriate transition period to discontinue sales. (NEMA, No. 51 at pp. 3–4) GE Lighting stated that following a new energy efficiency standard, Congress has generally provided three years for manufacturers to prepare for a transition of products followed by an unlimited amount of time to sell through existing inventory. (GE Lighting, No. 59 at p. 2) NEMA also commented that the statutory scheme reflects Congressional intent that manufacturers and retailers have at least three years to plan for and adjust to any sales restrictions. (NEMA, No. 51 at p. 4) NEMA stated that Congress makes laws with due regard to market forces and therefore Congressional intent is that DOE act with global market forces and consumer demand in mind when exercising agency authority. (NEMA, No. 51 at p. 2) NEMA stated that while supply and demand for incandescent lamps is declining, demand persists and in a free market economy manufacturers and retailers respond by supplying products. (NEMA, No. 51 at p. 2) NEMA stated that a 60-day transition period is inconsistent with that Congressional intent and a transition period of 365 days, though two years sooner than Congress intended, would give manufacturers necessary time to adjust to the sales ban. NEMA also commented that while the Administrative Procedure Act requires a minimum of 30 days before a rule may become effective, it does not set a maximum period for an effective date. (NEMA, No. 51 at p. 4)

GE Lighting commented on its understanding that DOE recognizes the practicalities of the transition to new standards and that this challenge can be mitigated through DOE's enforcement discretion. GE Lighting further supported NEMA's proposal to phase in

the regulation in three steps. (GE Lighting, No. 59 at p. 2) NEMA and GE Lighting requested that DOE clearly state specific enforcement timelines to avoid negative outcomes for businesses and ensure availability of lighting for consumers. (NEMA, No. 51 at p. 4; GE Lighting, No. 59 at p. 2) NEMA stated that the proposed regulatory text in the December 2021 NOPR (see 86 FR 70755, 70770) would impose an immediate ban on sales of covered lamps and is inconsistent with DOE's statements in the December 2021 NOPR regarding enforcement discretion. (NEMA, No. 51 at p. 5)

NRF and RILA stated they want to ensure changes resulting from the 45 lm/W backstop implementation do not cause adverse environmental and economic impacts and are widely accepted by consumers. (NRF and RILA, No. 55 at p. 2)

CEC stated that, while it agrees with the DOE's stated concerns regarding the potential immediate imposition of a sales prohibition, DOE's proposal to exercise its enforcement discretion is inconsistent with EPCA and Congressional intent. (CEC, No. 53 at p. 3) CEC stated that Congress provided manufacturers with notice that if DOE did not meet its statutory obligations by January 1, 2017, there would be a mandatory sales prohibition on any GSL, as defined, that could not meet a minimum efficacy of 45 lm/W. CEC stated that DOE indicated the backstop would be automatically triggered as early as March 17, 2016. CEC asserted that on January 1, 2017, manufacturers knew that DOE had not met the statutory requirements. CEC argued that stakeholders knew or should have known, three years in advance, that EPCA's backstop sales prohibition would be in effect on January 1, 2020. CEC further argued that Congressional intent is for DOE to enforce the backstop for all noncompliant GSLs, as defined by EPCA, immediately, without exercising its enforcement discretion. (CEC, No. 53 at pp. 3–4) Additionally, CEC asserted that because Congress provides state Attorneys General with the authority to enforce the ''applicable standard established under section 6295(i)'' against any GSIL that doesn't meet the standard, state Attorneys General could enforce the backstop to ensure consumer protection in their states regardless of DOE's enforcement discretion. (CEC, No. 53 at p. 4; *citing* 42 U.S.C. 6304)

In this document, DOE has determined that the backstop provision in 42 U.S.C. 6295(i)(6)(A)(v) has been triggered and the Secretary must prohibit the sale of any GSL that does not meet a minimum efficacy standard of 45 lm/W. DOE recognizes that implementation of the backstop, which is a sales prohibition, presents different challenges than most DOE standards, which are based on the date of manufacture. DOE recognizes that a transition period is often necessary for the market to adjust to the implementation of a standard.

Congress structured 42 U.S.C. 6295(i)(6)(A)(i)–(v) so as to provide manufacturers with a lead time (with a possible shorter lead time for California and Nevada) to adjust to different efficacy standards—either standards adopted by DOE through rulemaking or the imposition of the statutory backstop. In addition, Congress expressly required DOE to consider phased-in effective dates by considering ''the impact . . . on manufacturers, retiring and repurposing existing equipment, stranded investments, labor contracts, workers, [ ] raw materials,'' and ''the time needed to work with retailers and lighting designers to revise sales and marketing strategies.'' 42 U.S.C. 6295(i)(6)(A)(iv). Therefore, Congress did not intend for there to be an instantaneous imposition of a new 45 lm/W efficacy standard for GSLs. Such a possible outcome exists now only because of DOE's delay in correctly addressing the applicability of the backstop. DOE must balance Congress's intent to facilitate a smooth transition to different efficacy standards through the provision of lead time with the clear intent of Congress that these different efficacy standards were to be in place as of January 1, 2020. 42 U.S.C. 6295(i)(6)(A)(jjj),(v). Hence, in order to provide for a smooth transition, DOE will account for the practicalities of this transition to Congress's backstop efficacy standard through use of its enforcement discretion.

As previously stated, once DOE determines that the backstop has been triggered, Congress provides a specific date on which the prohibition begins—January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v)). However, as noted, DOE understands the practicalities associated with an immediate implementation of the 45 lm/W backstop standard for GSLs and therefore, will issue guidance regarding enforcement of the standard. DOE's enforcement guidance will be applicable to all states (except for California and Nevada, see section II.A.3).

The enforcement guidance will be informed, in part, by the comments received to the May 2021 RFI and December 2021 NOPR. In the December 2021 NOPR, DOE discussed the comments received on enforcement in the May 2021 RFI. DOE also received several comments on the December 2021 NOPR regarding enforcement including the date of enforcement, phased-in enforcement approach, and consumer education. These comments are discussed in the following sections.

1. Prompt Enforcement

DOE received comments recommending DOE begin enforcing the 45 lm/W backstop requirement as soon as possible. SC, NRDC, and EJ stated that in light of delays, DOE should act swiftly to finalize the proposed rule and begin enforcing EPCA's backstop. (SC, NRDC, and EJ, No. 58 at p. 1) CEC, SC, NRDC, and EJ, ASAP et al., and NASEO stated that DOE missed the December 31, 2021 deadline set by President Biden in Executive Order 13990 to complete the review of the backstop rule. (CEC, No. 53 at p. 3; SC, NRDC, and EJ, No. 58 at p. 2; ASAP *et al.,* No. 63 at pp. 1–3; NASEO, No. 45 at p. 1) SC, NRDC, and EJ stated that the White House's Office of Information and Regulatory Affairs (''OIRA'') took approximately two and a half months to review the December 2021 NOPR pursuant to E.O. 12886, and that this pace fails to reflect that the December 2021 NOPR is simply corrections of unlawful legal interpretations from the prior administration. SC, NRDC, and EJ urged DOE to cease what they characterized as its ongoing, unlawful efforts to avoid implementing the transformative advance in lighting efficiency that Congress enacted in 2007. (SC, NRDC, and EJ, No. 58 at p. 2)

SC, NRDC, and EJ, CFA and NCLC, CEC, CA IOUs, ASAP et al., NASEO, the Attorneys General, and IPI et al. stated that DOE should implement prompt enforcement of the backstop standard. (CEC, No. 53 at p. 5; CA IOUs, No. 56 at pp. 2, 4; SC, NRDC, and EJ, No. 58 at p. 2; ASAP et al., No. 63 at p. 3; NASEO, No. 45 at p. 1; CFA and NCLC, No. 52 at p. 3; Attorneys General, No. 60 at pp. 2, 3, 4; IPI et al., No. 54 at p. 3) CEC stated that DOE should not exercise its proposed enforcement discretion, as it would allow manufacturers to shift the costs of inefficient and unlawful lighting onto the environment and consumers. (CEC, No. 53 at p. 3) CEC added that exercising enforcement discretion would undermine President Biden's commitment to addressing the climate crisis. (CEC, No. 53 at pp. 1–2) CEC asserted that the law regarding the statutorily required implementation of the backstop is clear, and stakeholders were on notice of the sales prohibition since January 1, 2017, and that DOE

should carry out enforcement immediately. (CEC, No. 53 at p. 2) CEC further stated that DOE is required to implement the backstop immediately, and that no environmental or economic analysis is required to implement the backstop. (CEC, No. 53 at pp. 2–3)

CEC, CFA, and NCLC asserted that each month of additional delay in backstop implementation costs consumers nearly $300 million in lost bill savings and results in 800,000 tons of carbon emissions. (CEC, No. 53 at p. 2; CFA and NCLC, No. 52 at pp. 1–2) ASAP et al. stated that inefficient GSLs sold during a six-month period add nearly 5 million metric tons (''MMT'') of carbon emissions to the atmosphere and cost consumers $1.8 billion in higher utility bills. ASAP et al. further stated that allowing lamp manufacturers to continue the manufacture and sale of inefficient lamps would benefit manufacturers at the expense of consumers and the planet. (ASAP et al., No. 63 at p. 3) CEC argued that although manufacturers and distributors may experience losses from stranded inventory, if inefficient GSLs are permitted to remain in the market consumers will experience higher energy bills and the grid will have unnecessary load. CEC further stated that DOE's proposed enforcement discretion is inconsistent with Executive Order 13990 and places unreasonable weight on stranded costs without accounting for economic and environmental costs to consumers and the environment. (CEC, No. 53 at pp. 4)

The Attorneys General cited DOE's estimates of savings from the backstop and stated that prompt implementation of the backstop will facilitate manufacturers' deployment of more efficient technologies, increase consumer choice, significantly reduce energy costs, and ensure equitable distribution of lighting efficiency benefits. (Attorneys General, No. 60 at pp. 1, 2–3) The Attorneys General stated that, in a recent GSL market survey of New York state commissioned by the NYSERDA, retailers and distributors reported that they rely on manufacturers to provide products that comply with regulatory requirements, and manufacturers revealed that they anticipate efficiency standards to increase in stringency but will not initiate product changes without a high level of certainty that the requirements will go into effect. The Attorneys General also stated the survey showed that LED lamps across product types are now widely available in New York. (Attorneys General, No. 60 at pp. 2–3) IPI et al. asserted that the backstop's net benefits are likely considerably higher than DOE's estimates due to perceived discrepancies in social cost estimates and discount rates. (IPI et al., No. 54 at p. 36) IPI et al. stated that DOE should implement the backstop as soon as possible to ensure the backstop's net benefits to the public are maximized and available earlier. (IPI et al., No. 54 at p. 36)

SC, NRDC, and EJ, CFA and NCLC, ASAP et al., NYSERDA, NASEO, and the Attorneys General stated that prompt implementation of the backstop standard will benefit low-income consumers. (SC, NRDC, and EJ, No. 58 at p. 2; NYSERDA, No. 48 at p. 2; Attorneys General, No. 60 at p. 3; CFA and NCLC, No. 52 at pp. 2, 3) ASAP et al. and NASEO stated that low- and moderate-income households spend a disproportionate share of their incomes on higher electric bills. (ASAP et al., No. 63 at pp. 1–2; NASEO, No. 45 at p. 1) ASAP et al. further stated that low-income households spend nearly ten times as much of their income on energy bills as other households, 10.4 percent compared to 1.2 percent. (ASAP et al., No. 63 at p. 2) The CFA and NCLC commented that most low-income households are typically renters who often have older preinstalled and less efficient incandescent lamps or CFLs. (CFA and NCLC, No. 52 at p. 2) SC, NRDC, and EJ, ASAP et al., NYSERDA, and the Attorneys General stated that low-income consumers often lack access to retailers that stock affordable, lasting, energy efficient lamps. (SC, NRDC, and EJ, No. 58 at p. 2; ASAP et al., No. 63 at p. 2) NYSERDA, CFA, and NCLC cited a 2018 study conducted by the University of Michigan which they stated found that retailers serving disadvantaged communities had higher availability of less efficient lamps or set prices higher than retailers in other communities. (CFA, NCLC, No. 52 at p. 2) NYSERDA further stated that while LED lamps made up 73 percent of all 2020 GSL sales in New York, over half the lamps in certain locations and through some sales channels were less efficient lamps. NYSERDA stated that DOE should limit enforcement discretion as it will deny savings from consumers most in need. (NYSERDA, No. 48 at p. 2) The Attorneys General stated that mandating the backstop standard would ensure that low-income consumers, who have fewer options for energy efficient lamps, do not unnecessarily purchase lamps that ultimately cost more to own and operate. (Attorneys General, No. 60 at p. 3)

NYSERDA encouraged DOE to implement the backstop immediately after the proposed 60 days for as many lamp types as possible, especially for popular A-lamps. NYSERDA also stated that DOE should consider the associated risks and rewards and provide thorough justification for any enforcement discretion decisions. (NYSERDA, No. 48 at pp. 2–3)

The NPC Council stated that it supported the proposed 60-day effective date if the backstop is implemented to allow manufacturers and retailers to transition existing inventory. The NPC Council supported DOE's exercise of its enforcement discretion, especially for small towns and rural areas where inventory turnover is slower, and consumers have less access to large retailers. The NPC Council, also commented that the delays to date in implementing the backstop have likely resulted in higher costs for consumers in those rural areas due to lack of access to low-cost LED lamps. (NPC Council, No. 46 at p. 2)

NEMA stated that commentators have overstated the energy savings from the backstop. (NEMA, No. 51 at p. 5) ALA opposed the proposed 60-day effective date arguing that it would not allow for a smooth transition and would cause economic damage to manufacturers and retailers. ALA recommended that DOE provide manufacturers and retailers a reasonable amount of time to fulfill existing supply contracts and sell through inventory without causing harmful financial losses. (ALA, No. 57 at p. 2) NEMA asserted that logistical, contractual, and other immutable challenges make 60 days insufficient for businesses to respond and for retailers to change their inventory to avoid empty shelves. (NEMA, No. 51 at p. 2) NEMA further stated that a 60-day effective date would potentially cause irrecoverable financial losses for U.S. businesses throughout the supply chain. (NEMA, No. 51 at p. 3) GE Lighting stated the backstop requirement eliminates all halogen and incandescent lamps manufactured at this time and that a 60-day effective date would adversely impact the availability of GSILs and substitute products, leading to significant market disruption and harm to manufacturers, component suppliers, and retailers. (GE Lighting, No. 59 at p. 2) Lutron stated that while LED lamps are expected to meet the 45 lm/W standard, compliance has additional burden and DOE should use its enforcement discretion to prevent unintended market disruption. (Lutron, No. 62 at p. 2)

NRF and RILA stated that the 60-day effective date is a significant challenge for the retail industry since retailers maintain a 6 to 12 months inventory of incandescent lamps for consumers who

have not transitioned to LEDs. (NRF and RILA, No. 55 at p. 2) Specifically, NRF and RILA stated that lower-income households have not transitioned to LED lamps at the same rates as higher-income households due to higher initial purchase costs. (NRF and RILA, No. 55 at p. 2) VALU Home Centers stated that while it supports the 45 lm/W backstop and mostly sells LED lamps, it would like to sell through the lamps that will not meet the backstop standard to avoid extra costs to vendors and retailers. (VALU Home Centers, No. 43 at p. 1)

DOE appreciates these comments relating to timing for enforcement of the 45 lm/W backstop standard. As previously noted in this rule, once DOE determines that the backstop has been triggered, Congress provides a specific date on which enforcement of the prohibition begins—January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v)). Since this date has already passed, DOE will use enforcement guidance to provide stakeholders with more certainty as to how they must comply with the new standard. This guidance will be released simultaneously with this rulemaking. DOE also notes that because this rule is a ''major rule'' under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act, the rule cannot be effective prior to 60 days after publication in the **Federal Register** as required by 5 U.S.C. 801. To ensure the effective date for the 2022 Definition Final Rule occurs before the effective date of this final rule so that the amended definitions of GSL, GSIL and the other supplemental definitions are final before the standards in this rule are effective, the 2022 Definition Final Rule has a 60-day effective date and this rule will be effective within 75 days of publication instead of the 60-day effective date as proposed. This will ensure that the full scope of GSLs subject to the backstop requirement is established before the sales prohibition for GSLs that do not meet the 45 lm/W backstop requirement goes into effect. Regarding comments related to the estimated energy savings, DOE address these comments in section II.D.1. of this document.

2. Phased-In Enforcement

NEMA and GE Lighting stated that the effective date of the backstop should be 12 months after the publication of the final rule. (NEMA, No. 51 at p. 4; GE Lighting, No. 59 at pp. 2–3) NEMA stated manufacturers need at least 12 months following the publication of the final rule to cease the production of incandescent/halogen lamps and adjust supply chains. (NEMA, No. 51 at p. 3) NEMA further stated that these timeline estimates are based on normal market conditions, independent of current supply and logistics challenges, and are optimistically short. (NEMA, No. 51 at p. 3) GE Lighting supported NEMA's proposal and added that the supply chain for incandescent lamps is both long and complicated, involving transportation to points of manufacture outside of the U.S., shipping all finished products to exporting foreign ports, and importation into the U.S. (GE Lighting, No. 59 at pp. 2–3)

NRF and RILA stated that some retailers will need at least a 12-month sell-through period beyond a manufacture-by date to fully deplete existing inventories, reduce unnecessary waste, and give consumers time to adjust to the new product mix. (NRF and RILA, No. 55 at p. 2) ALA further stated that separate sales ban dates for retailers and manufacturers are necessary to allow retailers to clear their inventory and avoid negative effects on the small businesses that make up the residential lighting industry. (ALA, No. 57 at p. 2) NEMA and GE Lighting stated that after the 12-month manufacture-by (import) date, two separate phases of sell-through for high-volume and lower-volume lamps should be included as part of DOE's enforcement discretion. NEMA stated that retailers would need a minimum of 12 months to sell through high-volume A-line GSIL and R30/BR30 IRL inventory, with additional time potentially necessary to sell through all other slow-moving GSLs and those newly added to the expanded definition of GSL. (NEMA, No. 51 at pp. 3–5) GE Lighting stated support for a 12-month sell-through of halogen A-line lamps and added that additional time, up to a second year, will be needed to clear inventory of slower moving products added per the expanded definition of GSL. (GE Lighting, No. 59 at p. 3)

NEMA stated that the COVID–19 pandemic has greatly complicated supply chain forces and has produced transportation and timing challenges outside the control of manufacturers or retailers. (NEMA, No. 51 at p. 2) NEMA stated that supply chain delays have persisted from 2020 through 2022 and include COVID protocols and lack of employees, logistics and shipping delays doubling lead times from 5–6 weeks to up to 10–12 weeks for imported products which are also greatly increasing shipping costs, and electronic chip shortages that are affecting LED lamp production. NEMA further stated that the pandemic's impacts have caused delays for everything from component sourcing to delivery of goods from the factory to the store shelf, and are persisting into 2022 with no immediate end in sight. (NEMA, No. 51 at p. 3) NEMA recommended that any definition of manufacturing considered in DOE's enforcement policy should allow for departure from foreign ports in recognition of the unprecedented and unpredictable supply chain activities. (NEMA, No. 51 at p. 4) GE Lighting stated that previously weeks-long processes now take months and that the three most pressing issues for increasing production and inventory of new LED lamps are electronic chip component shortages, shipping and port delays for imported products, and COVID-related production delays. (GE Lighting, No. 59 at p. 3) NEMA asserted that DOE has an obligation to protect U.S. businesses, manufacturers, and retailers from unnecessary negative financial impacts and encouraged DOE to review all past NEMA comments on the backstop rule and its implementation. (NEMA, No. 51 at pp. 2, 5)

DOE is aware of the near-term supply chain issues resulting from the on-going COVID–19 pandemic. In June 2021, the Short-Term Supply Chain Disruptions Task Force (''Task Force'') was created and is led by the U.S. Department of Transportation, the U.S. Department of Commerce, and the U.S. Department of Agriculture, and the Task Force focuses on the mismatch of supply and demand in semiconductors, among other issues.[12] The Task Force has moved ports toward 24/7 operations and reduced long-dwelling containers sitting on the docks.[13] Moreover, on February 23, 2022, the U.S. Department of Transportation announced $450 million of funding available for ports across the country to make infrastructure upgrades.[14] While these and other efforts have been undertaken to address supply-chain issues, DOE acknowledges that issues remain on-going.

Further, DOE recognizes the sell-through issue that arises because the backstop requirement is a sales prohibition, and that manufacturers and retailers may have been disadvantaged by DOE's position changes regarding whether the backstop requirement has been triggered. In using its enforcement discretion, DOE will consider the near-term market and supply chain

[12] *www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities/.*

[13] *www.transportation.gov/briefing-room/dot-lays-out-actions-strengthen-supply-chains-and-revitalize-economy.*

[14] *www.transportation.gov/briefing-room/dot-lays-out-actions-strengthen-supply-chains-and-revitalize-economy.*

environment to provide the necessary flexibility to avoid undue market disruption.

The CA IOUs commented that although DOE's use of enforcement discretion will decrease energy savings, they support DOE's application of short-term enforcement discretion that is based on transparent market data, to protect consumers from market disruptions outside of California following implementation of the backstop. The CA IOUs stated that enforcement discretion can prevent temporary shortages of low-volume GSLs that are currently less common in LED versions but should not be applied to GSILs, IRLs, or other popular, widely available GSLs. The CA IOUs recommended that industry demonstrate which GSL types necessitate enforcement discretion by making available their supply of LED GSL inventory and showing that the supply chain is insufficient to meet demand. The CA IOUs stated that any DOE enforcement discretion applied should end no later than 12 months following the effective date of the GSL backstop. (CA IOUs, No. 56 at p. 3)

DOE acknowledges the importance of avoiding market disruptions for manufacturers, retailers, and consumers, which DOE will consider in using its enforcement discretion. DOE also agrees that use of its enforcement discretion should be transparent, which is why DOE will issue an enforcement policy prescribing how its enforcement discretion will be applied.

Minimise USA stated that while the backstop requirement may cost manufacturers billions of dollars in potential profits, any transition period for compliance should only be afforded to U.S. companies that manufacture products completely in the United States, and only a one-year transition period be given for the sale of existing inventory that has been manufactured on or before the date of the final rule. Minimise USA stated that DOE should not consider China's request for a transition period of at least three years. Minimise USA stated that the debate regarding the 45 lm/W requirement has been ongoing for five years, which was sufficient time for manufacturers to be positioned for implementation of the standard. (Minimise USA, No. 38 at p.1) As stated, Congress has provided the specific date on which the backstop sales prohibition begins, and DOE seeks to give meaning to that mandate even though the date has passed. In exercising its enforcement discretion to avoid market disruption, the enforcement policy is being made public to foster transparency and equal application to all manufacturers.

Lutron stated that having to re-test LED lamps to meet the DOE requirement of testing in a National Voluntary Laboratory Accreditation Program (''NVLAP'') accredited lab will be burdensome, particularly for small and medium sized lamp companies that have only made LED lamps. Lutron also stated that GSLs such as LED lamps with 50,000-hour lifetimes may require a full year of testing to certify compliance and the option of de-rating lamp lifetimes would confuse consumers. Lutron stated that given retesting time, DOE should consider an 18–24 month phase-in period, thereby preventing the risk of lower adoption of LEDs resulting from marketplace confusion. (Lutron, No. 62 at p. 2) Once the backstop is triggered, Congress directs DOE to prohibit the sale of any GSL that does not meet a minimum efficacy standard of 45 lm/W. (42 U.S.C. 6295(i)(6)(A)(v)) Regarding testing by an accredited laboratory, DOE requires testing of GSLs be conducted by test laboratories accredited by an Accreditation Body that is a signatory member to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). A manufacturer's or importer's in-house laboratory, if accredited, may conduct the applicable testing. 10 CFR 430.25. NVLAP is a signatory of ILAC MRA. Manufacturers must make representations with respect to the energy use or efficiency of integrated LED lamps per DOE's test procedure in appendix BB to subpart B of 10 CFR part 430 (appendix BB). Thus, manufacturers selling integrated LED lamps should already be testing their products at an accredited laboratory as specified in 10 CFR 430.25. Regarding the LED lamp lifetime, the statutory requirement implemented in this rule does not establish a standard on lifetime.

3. Consumer Education

NEMA commented that the December 2021 NOPR did not address education and communication to manage potential negative consumer reactions. NEMA provided examples of such communication, including manufacturers and retailers creating point of purchase material and signage, identifying and coding cross-referencing options, developing and posting web page content, and planning and implementing employee training to reliably assist consumers. NEMA stated that considerable time was put into such efforts leading into the 2012–2014 incandescent phaseout to ensure that consumers were not surprised when certain lamp types were not on shelves. NEMA encouraged DOE to acknowledge the lead times necessary to ensure a smooth transition by allowing time for education and communication. (NEMA, No. 51 at p. 4)

EEI stated that increasing consumer education as part of implementation of the backstop requirement would ensure a smooth and flexible market transition for consumers, including electric companies operating significant demand side management programs. (EEI, No. 61 at p. 2) GE Lighting stated that time is needed for retailers to educate those consumers that buy halogen and incandescent lamps on the issues and benefits of converting to LED technology, as well as to change and plan new LED store sets during the retailer reset period in the spring or fall. (GE Lighting, No. 59 at p. 3)

DOE agrees that consumer education can facilitate market transition and consumer acceptance of new technologies and notes the availability of existing consumer education resources. LED technology is not a new technology and, as indicated by commenters, occupies a substantial share of the lighting market. A number of big box retailers have moved to selling only LED lighting. [15] Retail locations also have provided displays to educate consumers on lamp selection, including on the selection of LED lamps to meet consumer needs. Moreover, DOE and ENERGY STAR have developed and made available educational materials to assist consumers in replacing incandescent lamps with LED lamps. *See e.g.,* ''LED Bulbs Made Easy'' (available at *www.energystar.gov/sites/default/files/asset/document/purchasing_checklist_revised.pdf;* DOE's Energy Saver (available at *www.energy.gov/energysaver/led-lighting*). In addition, the Federal Trade Commission maintains a website that contains significant consumer- and manufacturer-focused content on lighting products available to all consumers and manufacturers at *www.ftc.gov/tips-advice/business-center/guidance/ftc-lighting-facts-label-questions-answers-manufacturers.*

DOE appreciates the comments received regarding the enforcement of the implementation of the backstop. DOE understands the challenges associated with inventory transition as well as the importance of ensuring lamps are available to consumers. As

[15] EPA, ''The Light Bulb Revolution,'' October 2017 available at *https://www.energystar.gov/sites/default/files/asset/document/LBR_2017-LED-Takeover.pdf.*

explained in the NOPR, DOE will issue an enforcement policy separately from this rulemaking, which will be informed by all of these comments. The policy will reflect DOE's balancing of the consumer benefits associated with energy bill savings, along with the need for a practical transition time for lamps to be sold through the distribution chain. In order to avoid negative outcomes for businesses and ensure availability of lighting for consumers, the enforcement policy will provide a clear timeline for implementation of the backstop at the point of manufacturer and at the point of sale for all general service lamps subject to the backstop.

Although DOE is not using this rulemaking to set an enforcement policy, DOE appreciates the input it received to help inform its policy, which DOE anticipates will evolve with experience. DOE's final enforcement policy to support the implementation of the Congressional backstop will be posted at *www.energy.gov/enforcement/.*

D. Impacts

DOE received several comments on the potential impacts of implementing the 45 lm/W backstop requirement including market trends and energy savings; benefits and costs to the consumer; features of LED lamps; and potential health and safety impacts of LED lighting. These comments are discussed in the following sections.

1. Market Trends and Energy Savings

NEMA commented that other commenters have overstated the energy savings potential resulting from the backstop requirement as the lighting market has already undergone a dramatic shift to LED lamps since the time this rulemaking began in 2014. NEMA stated that a small part of the market continues to choose halogen lamps due to personal preferences for dimming, color appearance, or simply first cost and that very few halogen lamps will be sold in half a decade due to market forces alone. NEMA further stated that additional savings potential from a DOE regulation is low compared to data reflecting savings already achieved from the market transition to LED lamps. (NEMA, No. 51 at p. 5) The Free Market Organizations asserted DOE failed to consider non-regulatory approaches and market forces have already resulted in the average lamp being 70 lm/W. They added that DOE has forecasted LED lamps will be 84 percent of the market by 2035 and industry data indicates that GSILs are no more than 18 percent of current sales. The Free Market Organizations further stated that overall energy savings resulting from the backstop standard will be minimal due to growth of LEDs and therefore, will not meet EPCA's requirement that an amended standard result in significant energy savings. (Free Market Organizations, No. 65 at pp. 5–6)

The CA IOUs commented that although market data show decreased savings potential from a national GSL standard, due to the market transition to LED lamps since 2017, the data also show that the size of the U.S. lighting market and the high energy efficiency of LED technology provide significant remaining savings potential. (CA IOUs, No. 56 at p. 2) The CA IOUs stated that they are not aware of technical barriers preventing market entry for LED alternatives of any GSL type. The CA IOUs asserted that LED lights of all types are available to U.S. consumers and the lighting industry has ample capacity to meet demand following the effective date of the GSL backstop, as LED products now dominate the most popular GSL shapes. (CA IOUs, No. 56 at p. 3)

The CA IOUs also commented that incandescent/halogen lamps continue to account for a significant market share for A-type lamps despite their higher life-cycle costs and the wide availability of LED alternatives. The CA IOUs stated that in 2020, incandescent/halogen lamps held a 33 percent share of the national A-type lamp market, which the lighting industry projected to decrease to 23 percent by the third quarter of 2021. The CA IOUs further stated that decorative and specialty incandescent/halogen GSLs also have a higher market share. (CA IOUs, No. 56 at p. 2) NEEA commented that in 2020, 82 percent of GSLs in stores met the 45 lm/W standard, and estimated that in the Northwest, LED and CFL products made up approximately 74 percent of all GSL sales. NEEA stated that this indicates that implementing the backstop will not adversely affect the market. (NEEA, No. 64 at p. 2) The Attorneys General commented that while the LED share of the overall lighting market in New York is over 70 percent, over half of the GSLs for sale in some locales are incandescent/halogen lamps. (Attorneys General, No. 60 at p. 1) CFA and NCLC stated that LED market share is about 60 percent and that the remaining 40 percent of sales are incandescent products that increase consumer costs. (CFA and NCLC, No. 52 at p. 2)

DOE is appreciative of information regarding market trends and energy savings. This is not a discretionary standards rulemaking subject to evaluation of the factors at 42 U.S.C. 6295(o). As noted in section II.A.3, this final rule determines that the backstop standard has been triggered because DOE failed to complete the first cycle of rulemaking as prescribed by EPCA in 42 U.S.C. 6295(i)(6)(A). However, consistent with Executive Order 12866, DOE notes that it has provided a cost-benefit analysis of implementing the 45 lm/W backstop for GSLs, which is discussed in greater detail for the public in section IV.A.

2. Benefits and Costs

The SC, NRDC, and EJ, ASAP et al., EEI, and NASEO supported implementation of the 45 lm/W backstop, citing reductions in air pollutants, carbon dioxide (''CO_2'') emissions, and electricity consumption. (SC, NRDC, and EJ, No. 58 at p. 2; ASAP et al., No. 63 at p. 1; EEI, No. 61 at p. 3) SC, NRDC, and EJ commented that applying the 45 lm/W backstop requirement to GSLs as proposed by DOE will result in more than $3 billion in net consumer benefits over 30 years. (SC, NRDC, and EJ, No. 58 at pp. 2–3) ASAP et al. and NASEO stated that per analysis performed for DOE, consumers will save an estimated $2.7 billion on an annualized basis and 222 MMT of cumulative avoided carbon dioxide-equivalent over the next 30 years from implementing the backstop standard. (ASAP et al., No. 63 at p. 2; NASEO, No. 45 at p. 1) Minimise USA commented that, according to ASAP, a phaseout of incandescent light lamps would reduce energy use for lighting and eliminate 9.5 MMT of CO_2 emissions per year. (Minimise USA, No. 38 at p.1) CEC stated that the LED alternative of a typical A-type 60 W incandescent lamp results in 80 percent energy savings. (CEC, No. 53 at p. 2) ASAP et al. commented that an average household with about 20 sockets will save more than $100 per year and an average household with more than 50 sockets will save more than $200 per year. (ASAP et al., No. 63 at p. 2) CFA and NCLC stated that switching one lamp from incandescent to LED saves $40–$90 over ten years which, using the midpoint of $65 and estimating 45 sockets in a household, translates to $3,000 net savings per household over ten years. (CFA and NCLC, No. 52 at p. 2) CEC stated that for a typical A-type 60 W incandescent lamp, any higher initial cost of the LED version is recovered in less than a year. (CEC, No. 53 at p. 2)

CFA and NCLC commented that LEDs are no longer a new, expensive lighting technology, and manufacturers can now produce LED lamps in almost every type of lamp that consumers purchase for

their homes. CFA and NCLC further stated that consumers who have switched to LED lamps have saved on energy costs and gained the convenience of not having to replace them as often due to their long life. (CFA and NCLC, No. 52 at p. 3) NEEA commented that based on its lighting market study, which includes point of sale data and in-person shelf surveys, LED products have grown since 2012 and their price has trended downwards. (NEEA, No. 64 at pp. 1–2) CFA and NCLC stated that a 2019 CFA survey found two-thirds of respondents support federal efficiency standards for lamps, compared to fewer than one-third who oppose standards. CFA and NCLC further stated that consumers that have had experience with LEDs are more likely to support efficiency standards compared to those who have no experience. CFA and NCLC stated that implementing the backstop standard will result in broader economic benefits, as cost savings in the commercial and industrial sectors are passed on to consumers through lower costs for goods and services, allowing money to be spent in other areas of the economy with greater multiplier effects. (CFA and NCLC, No. 52 at p. 2)

NASEO commented that the backstop requirement is important to the states, which rely on cost-effective federal appliance and equipment energy efficiency standards to help them meet their energy affordability, air quality, climate, electric reliability, and energy resilience goals. (NASEO, No. 45 at p. 1)

Project 21 stated that adopting the 45 lm/W backstop standard for GSLs will benefit LED manufacturers at the expense of companies that provide Edison lamps and consumers that will no longer have the choice of cost and features provided by Edison lamps. Project 21 stated that in the December 2019 Final Determination, DOE had determined not to implement the 45 lm/W backstop because it would harm consumers and would increase the cost of Edison lamps by 300 percent, resulting in a lamp costing approximately $8.10. Project 21 stated this DOE's prior determination recognized the trend towards LEDs and continued research in new technologies while making existing options affordable. Further, Project 21 commented that the cost of LEDs and incandescent lamps is not comparable and low-income consumers will be forced to pay more. (Project 21, No. 44 at pp. 1–2) Project 21 stated that EPCA allows DOE to revise standards for lamps and other appliances but does not intend for the executive branch to wield arbitrary power over the kinds of appliances consumers can use. (Project 21, No. 44 at p. 1) Hough opposed the backstop requirement, commenting that 36 percent of the American lamp market, *i.e.,* incandescent lamps used in approximately 2 billion sockets, would become illegal. Hough stated that the requirement needlessly micromanages the economy and sides with green special interests that deny choice and affordable options. Hough stated the backstop requirement will make Edison lamps including candelabra base, globe shape, and colored lamps prohibitively expensive to produce (*i.e.,* as much as 300 percent over current costs). (Hough, No. 39 at p. 1) One anonymous commenter stated that claims that switching to LED lighting will save consumers up to $300 per year do not seem possible as their lighting costs were $96 per year prior to moving to LED lamps. This commenter expressed hope that DOE uses realistic estimates. (Anonymous, No. 50 at p. 1)

The Free Market Organizations stated their support for DOE's determination not to set more stringent standards in the December 2019 Final Determination as such standards would have eliminated incandescent lamps by making them prohibitively expensive, costing consumers more than could be earned back in energy savings. They stated DOE has the authority to reassess the existing standard for GSILs, not by imposing a 45 lm/W standard but by considering an amended standard. They added that the review process for an amended standard under EPCA cannot prioritize efficiency above all else and must also ensure products remain available and product features, performance and reliability are preserved for consumers. (Free Market Organizations, No. 65 at p. 2)

As noted in section II.A.3 of this document, this is a non-discretionary rulemaking, not a routine standards rulemaking that considers all the factors under 42 U.S.C. 6295(o). Instead, Congress mandated the 45 lm/W backstop requirement if the Secretary fails to complete a rulemaking in accordance with clauses (i) through (iv) of 42 U.S.C. 6295(i)(6)(A) or if the final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W. As explained, DOE has determined that it failed to satisfy these statutory criteria. As such, the backstop requirement has been triggered.

While analysis is not statutorily required to implement the backstop requirement once triggered, consistent with E.O. 12866 DOE did conduct a cost-benefit analysis of implementing the 45 lm/W backstop for GSLs. DOE estimated the annualized national economic costs and benefits associated with the implementation of the 45 lm/W backstop relative to a no-new standard case. DOE first considered the product price and energy use of commercially available lamp options in the GSL definition, including those that would be prohibited under implementation of the 45 lm/W backstop and more efficacious GSLs that would continue to be available. DOE then developed a shipments model to project GSL shipments for a thirty-year period between 2022–2051 in the no-new-standard case and for the 45 lm/W backstop case. Shipments were estimated using a consumer-choice model sensitive to first cost, energy savings, lamp lifetime, and the presence of mercury. The shipments analysis also considered the impact of price learning on product price. Based on the shipments projections, DOE calculated the national consumer economic impacts of the 45 lm/W backstop by comparing the total installed product costs and operating costs in the 45 lm/W backstop case to the no-new-standards case.

DOE also analyzed the reduction in several greenhouse gases that would result from the expanded GSL definition and the 45 lm/W backstop using emissions intensity factors intended to represent the marginal impacts of the change in electricity consumption associated with amended or new standards.[16] As part of the development of this final rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, nitrous oxide (''N_2O''), and methane (''CH_4'').

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21-cv-1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on

[16] The methodology is described in ''Utility Sector Impacts of Reduced Electricity Demand'' (Coughlin, 2014; Coughlin 2019).

the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

For the purpose of complying with the requirements of Executive Order 12866, DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant (*i.e.,* SC–GHGs). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive Orders and guidance, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions (*i.e.,* SC–GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG) (IWG, 2021).[17] The SC–GHGs is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, SC–GHGs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHGs therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD), the DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer-reviewed science.

The SC–GHGs estimates are presented in DOE's technical support document (''TSD'') [18] and were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, in 2009, an interagency working group (IWG) that included the DOE and other executive branch agencies and offices was established to ensure that agencies were using the best available science and to promote consistency in the social cost of carbon ($SC–CO_2$) values used across agencies. The IWG published $SC–CO_2$ estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (IAMs) that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity (ECS)—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane ($SC–CH_4$) and nitrous oxide ($SC–N_2O$) using methodologies that are consistent with the methodology underlying the $SC–CO_2$ estimates. The modeling approach that extends the IWG $SC–CO_2$ methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The $SC–CH_4$ and $SC–N_2O$ estimates were developed by Marten et al. (2015) and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the $SC–CO_2$ estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the $SC–CO_2$ estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the $SC–CO_2$ estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017). Shortly thereafter, in March 2017, President Trump issued Executive Order 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure $SC–CO_2$ estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)).

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021, specifically the $SC–CH_4$ estimates, are used here to estimate the climate benefits for this rulemaking. The E.O. instructs the IWG to undertake a fuller update of the SC–GHG estimates by January 2022 that takes into consideration the advice of the National Academies (2017) and other recent scientific literature.

The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways. First, the IWG found that a global perspective is essential for SC–GHG

[17] *See* Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[18] *www.regulations.gov/.*

estimates because it fully captures climate impacts that affect the United States and which have been omitted from prior U.S.-specific estimates due to methodological constraints. Examples of omitted effects include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, and tourism, and spillover pathways such as economic and political destabilization and global migration. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this final rule DOE centers attention on a global measure of SC–GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. Prior to that, in 2008 DOE presented Social Cost of Carbon (SCC) estimates based on values the Intergovernmental Panel on Climate Change (IPCC) identified in literature at that time. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

While the IWG works to assess how best to incorporate the latest, peer reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: An average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3 percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

The SC–CO_2 values used for this final rule were generated using the values presented in the 2021 update from the IWG's February 2021 TSD. The SC–CO_2 estimates from the latest interagency update are presented in DOE's TSD. For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CO_2 values, as recommended by the IWG.[19] DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case.

The SC–CH_4 and SC–N_2O values used for this final rule were generated using the values presented in the 2021 update from the IWG.[20] The SC–CH_4 and SC–N_2O estimates from the latest interagency update are presented in DOE's TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC–N_2O values, as recommended by the IWG. DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case.

The estimated monetary health benefits from the reduced emissions of sulfur dioxides (''SO_2'') and nitrogen oxides (''NO_X'') emissions was estimated based on the latest benefit per ton estimates for the relevant sector from the EPA's Benefits Mapping and Analysis Program.[21]

DOE converted the time-series of costs and benefits into annualized values based on the present value in 2022, as shown in Table IV.1, and cumulative economic costs and benefits in Table IV.2. DOE calculated the present value using discount rates of 3 and 7 percent for consumer costs and health benefits from the reduction of SO_2 and NO_X emissions and case-specific discount rates for the value of the other greenhouse gas (''GHG'') (CO_2, N_2O, and CH_4) reduction benefits. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown in Table IV.1 and Table IV.2, but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates.

EEI commented that DOE should utilize metrics in its cost and benefit calculations for the backstop regulations that reflect the ongoing efforts by the electric sector on reducing emissions and deploying clean energy. EEI suggested specifically that the site to power plant conversion factor utilized in the previous modeling was outdated. (EEI, No. 61 at p. 3)

DOE notes that in both the LBNL report cited in the December 2021 NOPR and in DOE's analysis for the final rule, the latest projections for the electric power sector from Energy Information Administration's Annual Energy Outlook 2021 were used, which reflect the ongoing and expected changes in U.S. electricity generation. In addition to addressing EEI's comment regarding the analytical baseline, this approach is conceptually consistent with DOE's approach in the March 2016

[19] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

[20] See Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[21] Estimating the Benefit per Ton of Reducing Directly-Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. *www.epa.gov/system/files/documents/2021–10/source-apportionment-tsd-oct-2021_0.pdf.*

NOPR, but with updated site to power plant conversion factors.

IPI et al. submitted comments on the application of the social cost of greenhouse gases in analysis associated with the December 2021 NOPR. (IPI et al., No. 54 at pp. 1–37). They stated that DOE should expand upon its rationale for adopting a global damages valuation and for the range of discount rates it applies to climate effects. Their key comments were as follows: (1) DOE should affirm that, in its expert judgment, the working group's social cost estimates are appropriate but conservative lower bounds that omit significant categories of climate damages; (2) DOE should provide additional justification for its reliance on global climate damage valuations, while considering additional analysis of domestic effects; (3) DOE should provide additional explanation for its discount rate choices and conduct sensitivity analysis using lower rates; (4) DOE should defend against common criticisms of the working group's methodology; (5) DOE should reconsider its timeframe for costs and benefits and disclose the social cost of greenhouse gas estimates it applies to year 2051; (6) The December 2021 NOPR's high net benefits suggest that DOE should favor early implementation of the backstop standard.

Comments (1) through (4) previously mentioned relate to the social cost of greenhouse gas emission estimates recommended by the IWG in its February 2021 TSD.

DOE used the estimates for the SC–GHG from the most recent update of the IWG in its February 2021 TSD. DOE has determined that the estimates from the February 2021 TSD (as described more below), are based upon sound analysis and provide well founded estimates for DOE's analysis of the impacts of the reductions of emissions anticipated from the final rule.

The SC–GHG estimates in the February 2021 TSD are interim values developed under E.O. 13990, for use until revised estimates of the impacts of climate change can be developed through a more comprehensive review based on the most recent science and economics. 86 FR 7037, 7040 (Jan. 25, 2021). The SC–GHG estimates used in this analysis were developed over many years, using a transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, an IWG that included DOE, the EPA and other executive branch agencies and offices used three integrated assessment models (IAMs) to develop the SC–CO_2 estimates and recommended four global values for use in regulatory analyses. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013. While DOE recognizes the potential for consumer and environmental benefits from the prohibition on the sale of GSLs with an efficacy of less than 45 lm/W, these monetized values for the estimated emissions reductions are presented for informational purposes. DOE reiterates that because the backstop requirement in 42 U.S.C. 6295(i)(6)(A)(v) has been triggered, the statute requires DOE to prohibit sales of GSLs that do not meet the minimum efficacy of 45 lm/W. This backstop requirement is statutorily prescribed by Congress and no further analysis is required for its implementation.

Regarding comment (5) mentioned previously, DOE clarifies that it estimates costs and benefits over the lifetime of GSLs shipped between 2022 and 2051. The final year of the analysis period is 2084. The SC–GHG values applied between 2051–2070 are the same as those used by the EPA in a recent regulation strengthening greenhouse gas emission standards for automobiles.[22] DOE derived values after 2070 based on the trend in 2060–2070 in each of the four cases. DOE's technical report provides the time-series of annual SC–GHG values.

Regarding comment (6) favoring early implementation, as discussed in section II.C of this document, Congress prescribed a specific date for the backstop sales prohibition once triggered. Recognizing the practicalities associated with the immediate implementation of the 45 lm/W backstop standard for GSLs, DOE will issue guidance regarding enforcement of the standard.

3. Features of LED Lamps

DOE received several comments regarding features of LED lamps. One anonymous commenter asked if DOE accounted for the lower power factors of LED lighting, which is at 70 percent for Energy Star lamps compared to incandescent lighting which have a 100 percent power factor). (Anonymous, No. 41 at p. 1) A separate anonymous commenter asked if DOE is considering the loss of energy savings due to the ''rebound effect'' of less dimming of LED lighting compared to incandescent due to some LED lamps not being dimmable, others not dimming as far as incandescent lamps, or some consumers replacing dimmers with toggle switches to lower the cost of switching from incandescent lamps to non-dimmable LED lamps. (Anonymous, No. 42 at p. 1) A third anonymous commenter stated that if 10 percent of lighting in a home is on a dimmer DOE should account for the cost of replacing incandescent dimmers with LED-compatible dimmers, and further stated that such dimmers cost anywhere from $20–50 and the cost of the electrician labor is at least $100 per visit. (Anonymous, No. 40 at p. 1) Project 21 stated LED lamps cannot dim the same way Edison lamps do and result in loss of aesthetics as they cannot function in older fixtures such as antique chandeliers. (Project 21, No. 44 at pp. 1–2) The Free Market Organizations stated that LED lamps are more efficient and longer-lasting but cost more than incandescent bulbs and have inferior dimming. (Free Market Organizations, No. 65 at p. 4)

As DOE has previously noted, this is not a discretionary standards rulemaking subject to evaluation of the factors at 42 U.S.C. 6295(o). However, consistent with E.O. 12866, DOE notes that it has provided a cost-benefit analysis of implementing the 45 lm/W backstop for GSLs, which is discussed in greater detail for the public in section IV.A. Power factor is the ratio of the real power (wattage used by the lamp) to the apparent power (voltage multiplied by current drawn by the lamp circuit and what the electrical grid must withstand). A low power factor indicates that the lamp circuit is drawing more current than is being utilized. DOE's review of the market indicates that there are a substantial number of LED lamps with a power factor of 0.9 or greater. It also indicates that dimmable versions of LED lamps are readily available as well as a wide range of LED lamps with decorative shapes such as bullet, candle, flare and globe. Additionally, in response to the August 2021 Definition NOPR, NEMA commented that the rapid shift of decorative lamps (*i.e.,* T-Shape, B, BA, F, G16–1/2, G25, G30, S and M–14 shapes) to LED technology has been occurring for over 9 years and is nearing completion by market forces alone. NEMA also estimated the total market volume of decorative lamps at 950 million; and 520 million out of 665 million on mostly switch-controlled sockets have already been converted to LED technology, with 285 million incandescent decorative lamps on dimmers that would need to switch to LED technology. (NEMA, EERE–2021–

[22] See EPA, Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis, Washington, DC, December 2021. Available at: *https://www.epa.gov/system/files/documents/2021-12/420r21028.pdf* (last accessed January 13, 2022).

BT–STD–001, No. 20 [23] at pp. 3–4) NEMA's estimations indicate that a substantive conversion to LED dimmer technology has been taking place for decorative lamps and therefore, is economically feasible for consumers. Additionally, dimming of solid-state lighting is the subject of continual research and development such as dim-to-warm LED products which can mimic the dimming of incandescent lamps.[24] DOE notes that while the costs of replacing dimmers is not quantified here, the cost is not significant with respect to the operating costs savings of LED lamps relative to incandescent lamps. Regarding the rebound effect, DOE clarifies that it assumed no rebound in its estimate of the annualized national economic costs and benefits as a result of the implementation of the backstop (see section IV.A), consistent with the analysis in the March 2016 NOPR and in the December 2019 Final Determination.

4. Potential Health and Safety Concerns

Sherman commented that they are unable to see clearly or spend more than a few minutes under LED or fluorescent lighting without severe problems such as headaches. (Sherman, No. 35 at p. 1) Maier asserted that the backstop requirement violates the Americans with Disabilities Act (''ADA'') and requested that incandescent lamps continue to be available. Maier referenced a comment on the DOE website, in which the commenter stated they have a disability and cannot tolerate LED lamps and states that such an individual is protected under the ADA to use incandescent lamps. Maier further stated that Title 2 of ADA requires that individuals be consulted before implementation of such standards and that Title 1 of ADA requires reasonable accommodation for those with disabilities. (Maier, No. 47 at p. 1)

As discussed, DOE is codifying the backstop requirement as mandated by EPCA. DOE notes that the backstop requirement does not mandate the use of a particular technology and instead prohibits the sale of lamps below a specified efficiency (*i.e.,* 45 lm/W). (42 U.S.C. 6295(i)(6)(A)(v)) Though the public comments do not include quantitative evidence of specific lighting technology characteristics relevant to health, DOE has considered these public comments. DOE researched studies and other publications to ascertain any known impacts of LED lamps on human health and has not found any evidence concluding that LED lighting used for general lighting applications directly results in adverse health effects.[25] Additionally, DOE notes that the ADA does not apply to DOE for purposes of this rule, as the ADA only applies to private employers and not Federal agencies. Individuals wishing to file complaints under the ADA can visit *www.ada.gov.*

Glass and Walton commented regarding their concerns with the detrimental effects of LED technology in transportation applications (*e.g.,* motor vehicle lamps, street lamps, construction equipment). (Glass, No. 36 at p. 1; Walton, No. 37 at pp. 1–2)

GSLs and GSILs are covered under Part B of EPCA, which authorizes the regulation of certain consumer products. For the purpose of Part B, the definition of ''consumer product'' excludes products used in automobiles. (*See* 42 U.S.C. 6291(1)) Further, covered GSILs do not include those consumer products designed solely for use in recreational vehicles and other mobile equipment. (*See* 42 U.S.C. 6292(a)) Additionally, the GSL definition adopted in the 2022 Definitions Final Rule excludes lamps with lumens greater than 3,300 lumens (see section II.B of this document). Streetlamps and lighting for construction applications are generally 5,000 lumens or greater. Further, the definition of GSL excludes street signal lamps. As such, the lamps relevant to the concerns raised by Glass and Walton are generally not covered as GSLs and are not subject to the backstop requirement.

Sherman commented that incandescent lamps provide additional warming which can offset heating costs and can be used to keep water pipes from freezing where otherwise a space heater is used, which can be a fire hazard. (Sherman, No. 35 at p. 1) Glass stated that LED lamps are uncomfortable and also disruptive to animal and plant life. (Glass, No. 36 at p. 1)

Regarding the ability of incandescent lamps to provide heat in certain circumstances (*e.g.,* to keep pipes from freezing), DOE notes that the statutory backstop requirement applies to GSLs, which as defined exempts infrared lamps which have the primary purpose of providing heat (see section II.B of this document).

DOE researched this issue and did not identify any studies indicating that LED lamps have an adverse impact on animal and plant life.

A private citizen commented that incandescent/halogen lamps are being banned while less-efficient gas lights are still allowed to be sold in the U.S. They stated that a gas light uses 2500 British thermal units (''Btu'') or 732 W to produce the same amount of light as a 60 W incandescent or a 42–43 W halogen lamp and has a continuously burning pilot light that uses energy. (Anonymous, No. 49 at p. 1)

The 45 lm/W backstop requirement is applicable to all GSLs, and is not specific to any one lighting technology such as incandescent or halogen lighting. Therefore, the sale of any lamp that meets the definition of a GSL and has an efficacy less than 45 lm/W will be prohibited.

III. Conclusion

DOE has determined that the statutory 45 lm/W backstop requirement that applies to GSLs in 42 U.S.C. 6295(i)(6)(A)(v) has been triggered. This final rule codifies the backstop requirement at 10 CFR 430.32.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

This final rule is an economically significant regulatory action under E.O. 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review by OIRA in the Office of Management and Budget (''OMB''). Pursuant to section 6(a)(3)(C) of the Order, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the regulatory action, together with, to the extent feasible, a quantification of those costs. This assessment can be found in DOE's technical report that accompanies this rulemaking and the methodology is summarized in section II.D.2 of this document.

[23] Available at *www.regulations.gov/docket/EERE–2021–BT–STD–0012.*

[24] U.S. Department of Energy, *Dim-to-Warm LED Lighting: Stress Testing Results for Select Products,* January 2020, available at *https://www.energy.gov/sites/default/files/2020/04/f73/ssl-d2w-led-stress-testing-2020.pdf.*

[25] European Commission, ''Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) Report,'' June 2018. Available at *https://ec.europa.eu/health/system/files/2019-02/scheer_o_011_0.pdf;* Cleveland Clinic, ''Are LED Lights Damaging Your Retina?'' August 9, 2019. Available at *https://health.clevelandclinic.org/are-led-lights-damaging-your-retina/;* Light Europe, ''Frequently Asked Questions on alleged LED health related issues,'' December 2016. Available at *https://www.lightingeurope.org/images/publications/general/FAQ_on_alleged_LED_related_health_issues_-_December_2016.pdf.*

TABLE IV.1—SUMMARY OF ANNUALIZED COSTS AND BENEFITS, 2022–2051

	Million 2020$/year		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	2,955.1	2,788.0	3,128.8
Climate Benefits *	591.0	571.1	606.0
Health Benefits **	1,100.5	1,063.8	1,128.2
Total Benefits †	4,646.6	4,422.9	4,863.0
Consumer Incremental Product Costs ‡	148.9	150.9	145.0
Net Benefits	4,497.7	4,272.0	4,718.1
7% discount rate			
Consumer Operating Cost Savings	2,864.5	2,725.3	3,010.0
Climate Benefits *	591.0	571.1	606.0
Health Benefits **	960.8	932.4	982.3
Total Benefits †	4,416.4	4,228.8	4,598.4
Consumer Incremental Product Costs ‡	177.6	180.3	173.0
Net Benefits	4,238.8	4,048.5	4,425.3

Note: This table presents the costs and benefits associated with all GSLs shipped in 2022–2051. These results include benefits to consumers which accrue after 2051 from the products shipped in 2022–2051. This analysis presents costs and benefits assuming compliance beginning in 2022. As DOE has explained, DOE will release enforcement guidance simultaneously with this rulemaking. If significant compliance behavior changes result from enforcement discretion, both benefits and costs could be reduced for the relevant years, although DOE expects the net benefits will not be significantly changed.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the global social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC–GHG point estimate. See the accompanying technical report for details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent.

† Total and net benefits include consumer, climate and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but the Department does not have a single central SC–GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the Federal government's appeal of that injunction or a further court order. The preliminary injunction enjoined the Federal government from relying on the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits in accordance with applicable Executive orders.

‡ Costs include incremental equipment costs as well as installation costs.

TABLE IV.2—SUMMARY OF CUMULATIVE MONETIZED ECONOMIC BENEFITS AND COSTS FOR ALL GSLS, 2022–2051

	Billion 2020$
3% discount rate	
Consumer Operating Cost Savings	59.7
Climate Benefits *	11.9
Health Benefits **	22.2
Total Benefits †	93.8
Consumer Incremental Product Costs ‡	3.0
Net Benefits	90.8
7% discount rate	
Consumer Operating Cost Savings	38.0
Climate Benefits *	11.9
Health Benefits **	12.8
Total Benefits †	62.7
Consumer Incremental Product Costs ‡	2.4
Net Benefits	60.4

Note: This table presents the costs and benefits associated with all GSLs shipped in 2022–2051 using a present year of 2022. These results include benefits to consumers which accrue after 2051 from the products shipped in 2022–2051.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the global social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC–GHG point estimate.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but the Department does not have a single central SC–GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the Federal government's appeal of that injunction or a further court order. The preliminary injunction enjoined the Federal government from relying on the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits in accordance with applicable Executive orders.

‡ Costs include incremental equipment costs as well as installation costs.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*energy.gov/gc/office-general-counsel*).

DOE reviewed this final rule under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. DOE is revising the Code of Federal Regulations to incorporate and implement the backstop requirement for general service lamps that Congress prescribed in EPCA. Because DOE is not imposing additional costs beyond those required by statute, DOE concludes and certifies that this final rule has no significant economic impact on a substantial number of small entities and the preparation of a FRFA is not warranted.

C. Review Under the Paperwork Reduction Act

This final rule imposes no new information or record keeping requirements. Accordingly, Office of Management and Budget clearance is not required under the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.*

D. Review Under the National Environmental Policy Act of 1969

DOE has analyzed this regulation in accordance with the National Environmental Policy Act (NEPA) and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for rulemakings interpreting or amending an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended. 10 CFR part 1021, subpart D, appendix A5. DOE has completed the necessary review under NEPA and has determined that this rulemaking qualifies for categorical exclusion A5 because it is amending a rule that does not change the environmental effect of the rule and otherwise meets the requirements for application of a categorical exclusion. *See* 10 CFR 1021.410. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this final rule. DOE's CX determination for this final rule is available at *energy.gov/nepa/categorical-exclusioncx-determinations-cx.*

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this final rule and has determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. 42 U.S.C. 6297. Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

This final rule codifies the sales prohibition of GSLs with an efficacy of less than 45 lm/W prescribed in 42 U.S.C. 6295(i)(6)(A)(v). As this final rule would incorporate requirements specifically set forth in law, an assessment under UMRA is not required and has not been conducted.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action is not a significant energy action because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this final rule.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

Signing Authority

This document of the Department of Energy was signed on April 26, 2022, by Kelly J. Speakes-Backman, Principal Deputy 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 April 28, 2022.

Treena V. Garrett,

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

For the reasons set forth in the preamble, DOE amends part 430 of chapter II of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Amend § 430.32 by:

■ a. Revising the introductory text to paragraphs (n)(5) and (6), (u)(1), and (x)(1);

■ b. Revising paragraphs (x)(2) and (3);
■ c. Revising the introductory text to paragraphs (bb)(1) and (2); and
■ d. Adding paragraph (dd).

The revisions and addition read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(n) * * *

(5) Subject to the sales prohibition in paragraph (dd) of this section, and except as provided in paragraph (n)(6) of this section, each of the following incandescent reflector lamps manufactured after November 1, 1995, shall meet or exceed the lamp efficacy standards shown in the table:

* * * * *

(6) Subject to the sales prohibition in paragraph (dd) of this section, each of the following incandescent reflector lamps manufactured after July 14, 2012, shall meet or exceed the lamp efficacy standards shown in the table:

* * * * *

(u) * * *

(1) Medium Base Compact Fluorescent Lamps. Subject to the sales prohibition in paragraph (dd) of this section, a bare or covered (no reflector) medium base compact fluorescent lamp manufactured on or after January 1, 2006, must meet the following requirements:

* * * * *

(x) * * *

(1) Subject to the sales prohibition in paragraph (dd) of this section, the energy conservation standards in this paragraph apply to general service incandescent lamps:

* * * * *

(2) Subject to the sales prohibition in paragraph (dd) of this section, each candelabra base incandescent lamp shall not exceed 60 rated watts.

(3) Subject to the sales prohibition in paragraph (dd) of this section, each intermediate base incandescent lamp shall not exceed 40 rated watts.

* * * * *

(bb) * * *

(1) Subject to the sales prohibition in paragraph (dd) of this section, rough service lamps manufactured on or after January 25, 2018 must:

* * * * *

(2) Subject to the sales prohibition in paragraph (dd) of this section, vibration service lamps manufactured on or after January 25, 2018 must:

* * * * *

(dd) *General service lamp.* Beginning July 25, 2022 the sale of any general service lamp that does not meet a minimum efficacy standard of 45 lumens per watt is prohibited.

[FR Doc. 2022–09477 Filed 5–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2021–BT–STD–0012]

RIN 1904–AF22

Energy Conservation Program: Definitions for General Service Lamps

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

ACTION: Final rule.

SUMMARY: On January 19, 2017, the U.S. Department of Energy (''DOE'') published two final rules adopting revised definitions of general service lamp (''GSL'') and general service incandescent lamp (''GSIL''), and other supplemental definitions, to go into effect January 1, 2020. (''January 2017 Final Rules''). Prior to that effective date, on September 5, 2019, DOE withdrew the revised definitions of GSL, GSIL, and the other supplemental definitions. Upon further review and consideration, on August 19, 2021, DOE published a notice of proposed rulemaking (''NOPR'') proposing to amend the definitions of GSL, GSIL and the other supplemental definitions as previously set forth in the January 2017 Final Rules. DOE responds to comments received on the NOPR in this final rule and adopts the definitions of GSL and GSIL and the associated supplemental definitions set forth in the January 2017 Final Rules as proposed in the NOPR.

DATES: The effective date of this rule is July 8, 2022. The incorporation by reference of other material listed in this rulemaking was approved by the Director of the Federal Register on March 23, 2009.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, 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, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2021-BT-STD-0012.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

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

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SUPPLEMENTARY INFORMATION:

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I. Synopsis of the Final Rule

In this final rule, DOE adopts its proposal in the NOPR to amend the current definitions of GSL and GSIL to be defined as previously set forth in the January 2017 Final Rules. *See* 82 FR 7276; 82 FR 7322. DOE has determined that the definitions are consistent with the congressional direction provided in the Energy Policy and Conservation Act (''EPCA'') and further the purposes set forth in EPCA, as well as in Executive Order (''E.O.'') 13990, ''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.'' 86 FR 7037 (Jan. 25, 2021). Additionally, as proposed in the NOPR, DOE adopts the supplemental definitions established in the January 2017 Final Rules, which relate to the definitions of GSL and GSIL. DOE is not determining whether standards for GSLs, including GSILs, should be amended in this rule. Rather, DOE is establishing the scope of lamps to be considered in such a determination.

II. Introduction

Amendments to EPCA in the Energy Independence and Security Act of 2007, Public Law 110–140 (''EISA'') directed DOE to conduct a number of rulemakings regarding coverage of lamps as GSLs and GSILs, and to evaluate energy conservation standards for such lamps. 42 U.S.C. 6295(i)(6)(A)–(B). Pursuant to this authority, DOE conducted a rulemaking to establish revised regulatory definitions for GSLs and GSILs. *See* 82 FR 7276 (Jan. 19, 2017); 82 FR 7322 (Jan. 19, 2017). Subsequently, DOE conducted a rulemaking in which it withdrew these revised definitions before they took effect. 84 FR 46661 (Sept. 5, 2019). The following paragraphs provide an overview of the authorities and final rules issued by DOE relevant to the definitions for GSL, GSIL, and related terms, as adopted in this final rule.

A. Authority

EPCA, as amended,[1] authorizes 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 [2] of EPCA, established the Energy Conservation Program for Consumer Products Other Than Automobiles. 42 U.S.C. 6291–6309. These products include GSLs, the subject of this rulemaking.

EPCA directs DOE to conduct two rulemaking cycles to evaluate energy conservation standards for GSLs. 42 U.S.C. 6295(i)(6)(A)–(B). GSLs are defined in EPCA to include GSILs, compact fluorescent lamps (''CFLs''), general service light-emitting diode (''LED'') lamps and organic light emitting diode (''OLED'') lamps, and any other lamps that the Secretary of Energy (''Secretary'') determines are used to satisfy lighting applications traditionally served by general service incandescent lamps. 42 U.S.C. 6291(30)(BB)(i), (CC)(i), (DD). The EPCA provision setting forth relevant definitions indicates that the term ''general service lamp'' in EPCA does not include any of the twenty-two lighting applications or bulb shapes explicitly not included in the definition of ''general service incandescent lamp,'' [3] or any general service fluorescent lamp or incandescent reflector lamp. 42 U.S.C. 6291(30)(BB)(ii).

For the first rulemaking cycle, EPCA directs DOE to initiate a rulemaking process prior to January 1, 2014, to consider two questions: (1) Whether to amend energy conservation standards for general service lamps to establish more stringent standards than EPCA specifies, and (2) whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' 42 U.S.C. 6295(i)(6)(A)(i). In developing such a rule, DOE must consider a minimum efficacy standard of 45 lumens per watt (''lm/W''). 42 U.S.C. 6295(i)(6)(A)(ii). Further, if the Secretary determines that the standards in effect for GSILs should be amended, EPCA provides that a final rule must be published by January 1, 2017, with an effective date at least three years after the date on which the final rule is published. 42 U.S.C. 6295(i)(6)(A)(iii). Additionally, EPCA directs that the Secretary shall consider phased-in effective dates after considering certain economic factors. 42 U.S.C. 6295(i)(6)(A)(iv). If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), or if a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a ''backstop'' under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard. 42 U.S.C. 6295(i)(6)(A)(v).

EPCA further directs DOE to initiate a second rulemaking cycle by January 1, 2020, to determine whether standards in effect for GSILs (which are a subset of GSLs) should be amended with more stringent maximum wattage requirements than EPCA specifies, and whether the exemptions for certain incandescent lamps should be maintained or discontinued. 42 U.S.C. 6295(i)(6)(B)(i). As in the first rulemaking cycle, the scope of the second rulemaking is not limited to incandescent lamp technologies. 42 U.S.C. 6295(i)(6)(B)(ii).

In addition to the two mandated rulemaking cycles, under the statutory definition of GSL, DOE has authority to include lamps as GSLs upon determining that they are ''used to satisfy lighting applications traditionally served by general service incandescent lamps.'' 42 U.S.C. 6291(30)(BB)(i)(IV).

B. March 2016 Notice of Proposed Rulemaking and October 2016 Notice of Proposed Definition and Data Availability

Pursuant to its statutory authority, DOE published a notice of proposed rulemaking (''NOPR'') on March 17, 2016, that addressed the first question that Congress directed it to consider—whether to amend energy conservation standards for GSLs (''March 2016 NOPR''). 81 FR 14528, 14629–14630 (Mar. 17, 2016). In that NOPR, DOE stated that it would be unable to undertake any analysis regarding GSILs and other incandescent lamps because of a then-applicable congressional restriction (''the Appropriations Rider''). See *Id.* at 81 FR 14528, 14540–14541. The Appropriations Rider prohibited

[1] 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).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[3] The statutory definition of ''general service incandescent lamp'' in EPCA does not include the following incandescent lamps: (I) An appliance lamp; (II) A black light lamp; (III) A bug lamp; (IV) A colored lamp; (V) An infrared lamp; (VI) A left-hand thread lamp; (VII) A marine lamp; (VIII) A marine signal service lamp; (IX) A mine service lamp; (X) A plant light lamp; (XI) A reflector lamp; (XII) A rough service lamp; (XIII) A shatter-resistant lamp (including a shatter-proof lamp and a shatter-protected lamp); (XIV) A sign service lamp; (XV) A silver bowl lamp; (XVI) A showcase lamp; (XVII) A three-way incandescent lamp; (XVIII) A traffic signal lamp; (XIX) A vibration service lamp; (XX) A G shape lamp (as defined in ANSI C78.20–2003 and C79.1–2002) with a diameter of 5 inches or more; (XXI) A T shape lamp (as defined in ANSI C78.20–2003 and C79.1–2002) [and] that uses not more than 40 watts or has a length of more than 10 inches; (XXII) A B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp (as defined in ANSI C79.1–2002 and ANSI C78.20–2003) of 40 watts or less. 42 U.S.C. 6291(30)(D)(ii). These are the ''exemptions'' from the statutory definition, some of which are ''discontinued'' by this rule, in accordance with 42 U.S.C. 6295(i)(6)(A)(i).

expenditure of funds appropriated by that law to implement or enforce: (1) 10 CFR 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps (''IRLs''). Under the Appropriations Rider, DOE was restricted from undertaking the analysis required to address the first question presented by Congress but was not so limited in addressing the second question—that is, DOE was not prevented from determining whether the exemptions for certain incandescent lamps should be maintained or discontinued. To address that second question, DOE published a Notice of Proposed Definition and Data Availability (''NOPDDA''), which proposed to amend the definitions of GSIL, GSL, and related terms (''October 2016 NOPDDA''). 81 FR 71794, 71815 (Oct. 18, 2016). Notably, the Appropriations Rider originally was adopted in 2011 and was readopted and extended continuously in multiple subsequent legislative actions. It expired on May 5, 2017, when the Consolidated Appropriations Act, 2017 was enacted.[4]

C. January 2017 Final Rules

On January 19, 2017, DOE published the January 2017 Final Rules concerning the definitions of GSL, GSIL, and related terms. 82 FR 7276; 82 FR 7322. The January 2017 Final Rules amended the definitions of GSIL and GSL by bringing certain categories of lamps within the definitions of GSIL and GSL that EPCA had exempted, including IRLs. See 82 FR 7312; 82 FR 7323. The January 2017 Final Rules related to the second question that Congress directed DOE to consider, regarding whether to maintain or discontinue ''exemptions'' for certain incandescent lamps. 42 U.S.C. 6295(i)(6)(A)(i)(II). The discontinuation of the exemption would render the lamp a GSIL (and therefore also a GSL), to the extent it would otherwise qualify as a GSIL. 82 FR 7277. DOE also considered whether other lamps should be included in the definition of GSL. 82 FR 7277. DOE stated that it would then either impose standards on these lamps pursuant to its authority to develop GSL standards or apply the 45 lm/W backstop standard prohibiting the sale of lamps not meeting a 45 lm/W efficacy standard. 82 FR 7276, 7277. The definitions in the January 2017 Final Rules were to become effective on January 1, 2020. 82 FR 7276, 7276; 82 FR 7322, 7322. The definitions will herein be referred to as the ''January 2017 Definitions.''

D. September 2019 Withdrawal Rule and Subsequent Review

With the removal of the Appropriations Rider in the Consolidated Appropriations Act, 2017, DOE was no longer restricted from undertaking the analysis and decision-making required to address the first question presented by Congress—that is, whether to amend energy conservation standards for GSLs, including GSILs. Thus, on August 15, 2017, DOE published a Notice of Data Availability and request for information (''NODA'') seeking data for GSILs and other incandescent lamps (''August 2017 NODA''). 82 FR 38613.

The purpose of the August 2017 NODA was to assist DOE in determining whether standards for GSILs should be amended. 42 U.S.C. 6295(i)(6)(A)(i)(I). Comments submitted in response to the August 2017 NODA also led DOE to reconsider the decisions it had already made with respect to the second question presented to DOE (whether the exemptions for certain incandescent lamps should be maintained or discontinued). 42 U.S.C. 6295(i)(6)(A)(i)(II). As a result of the comments received in response to the August 2017 NODA, DOE also re-assessed the legal interpretations underlying certain decisions made in the January 2017 Final Rules. On February 11, 2019, DOE published a NOPR proposing to withdraw the revised definitions of GSL and GSIL, and the new and revised definitions of related terms that were to go into effect on January 1, 2020. 84 FR 3120 (''February 2019 Withdrawal NOPR''). In a final rule published September 5, 2019, DOE finalized the withdrawal of the definitions of GSIL, GSL, and related terms established in the January 2017 Final Rules. 84 FR 46661 (''September 2019 Withdrawal Rule''). Informed, in part, by comments received in response to the August 2017 NODA, DOE concluded in the September 2019 Withdrawal Rule that maintaining the definitions for GSL and GSIL as established by EPCA and not discontinuing certain exemptions pursuant to the required review under 42 U.S.C. 6295(i)(6)(A)(i) was the best reading of the statute. 84 FR 46661, 46665–46666. DOE also stated that it identified inaccuracies underlying its determination to revise the definitions of GSL and GSIL. 84 FR 46661, 46665. Based on data received in response to the August 2017 NODA, DOE learned that it had overestimated shipment numbers for candelabra base incandescent lamps by a factor of more than two. *Id.* In withdrawing the definitions established in the January 2017 Final Rules, DOE specifically addressed its determinations to maintain the exemptions for rough service lamps; shatter-resistant lamps; three-way incandescent lamps; high lumen incandescent lamps (2,601–3,300 lumens); vibration service lamps; T-shape lamps of 40 watts (''W'') or less or length of 10 inches or more; B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps of 40 W or less; candelabra base lamps; and IRLs. Id.

The September 2019 Withdrawal Rule also addressed issues and comments regarding the imposition of the 45 lm/W backstop, applicability of EPCA's anti-backsliding provision at 42 U.S.C. 6295(o), and preemption of State regulation of lamps. 84 FR 46663–46665, 46669. Although these additional issues concern DOE's regulation of lamps, they are not the subject of this NOPR. DOE has requested comments and data to inform further consideration of the 45 lm/W backstop provision. *See* 86 FR 28001 (May 25, 2021).

As a result of the September 2019 Withdrawal Rule, the amended definitions of GSL and GSIL and the new and revised definitions of related terms established in the January 2017 Final Rules were withdrawn prior to going into effect. The current regulatory definitions of GSL and GSIL are those set forth in EPCA. *See* 10 CFR 430.2; see also 42 U.S.C. 6291(30)(D); 42 U.S.C. 6291(30)(BB).

Subsequent to the September 2019 Withdrawal Rule, on January 20, 2021, President Biden issued E.O. 13990. Section 1 of that Order lists a number of policies related to the protection of public health and the environment, including reducing greenhouse gas emissions and bolstering the Nation's resilience to climate change. 86 FR 7037, 7041. Section 2 of the Order instructs all agencies to review ''existing regulations, orders, guidance documents, policies, and any other similar agency actions . . . promulgated, issued, or adopted between January 20, 2017, and January 20, 2021, that are or may be inconsistent with, or present obstacles to, [these policies].'' *Id.* Agencies are then directed, as appropriate and consistent with applicable law, to consider suspending, revising, or rescinding these agency actions and to immediately commence work to confront the climate crisis. *Id.* Consistent with E.O. 13990,

[4] *See* Consolidated Appropriations Act of 2017 (Pub. L. 115–31, div. D, tit. III); *see also* Consolidated Appropriations Act, 2018 (Pub. L. 115–141).

DOE has undertaken a review of the definitions of GSL and GSIL in the September 2019 Withdrawal Rule and the January 2017 Final Rules. Although E.O. 13990 triggered DOE's review, DOE is relying on its analysis below, based on the language and intent of EPCA, to support its decision to reconsider the September 2019 Withdrawal Rule. As a result of this review, DOE rejects the alternative interpretation of the statutory directives in EPCA set forth in the September 2019 Withdrawal Rule and determines that DOE's interpretation in this final rule is the best reading of the statute.

E. August 2021 Notice of Proposed Rule

On August 19, 2021, DOE published a NOPR that proposed to amend the definitions of GSL and GSIL as previously set forth in the January 2017 Final Rules. (''August 2021 NOPR''). 86 FR 46611. DOE received 17 written comments in response to the August 2021 NOPR from the interested parties listed in Table II.1.

TABLE II.1—AUGUST 2021 NOPR WRITTEN COMMENTS

Commenter(s)	Abbreviation	Commenter type
Anonymous	Anonymous	Private Citizen.
Anonymous	Anonymous	Private Citizen.
Anonymous	Anonymous	Private Citizen.
Anonymous	Anonymous	Private Citizen.
Northwest Power and Conservation Council	NPCC	Interstate Compact Agency.
National Association of State Energy Officials	NASEO	State Government Officials.
National Electrical Manufacturers Association	NEMA	Industry Association.
New York State Energy Research and Development Authority	NYSERDA	Efficiency Organization.
Attorneys General of New York, California, Colorado, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Vermont, Washington, The Commonwealth of Massachusetts, The District of Columbia, and The City of New York.	AGs	State Government Officials.
Lutron Electronics Co., Inc	Lutron	Manufacturer.
State of Washington Department of Commerce	State of Washington DOC	State Government Agency.
GE Lighting, a Savant Company	GE Lighting	Manufacturer.
California Energy Commission	CEC	State Government Agency.
Consumer Federation of America, National Consumer Law Center, Alliance for Affordable Energy, Consumer Action, Citizens Action Coalition of IN, Consumer Federation of California, Columbia Consumer Education Council, Pennsylvania Utility Law Project, TURN-The Utility Reform Network, Public Utility Law Project of New York, Virginia Citizens Consumer Council.	The Joint Comment	Consumer Advocacy Organizations.
California Investor-Owned Utilities	CA IOUs	Utility.
Sierra Club, Natural Resources Defense Council, Earthjustice	SC, NRDC, and EJ	Environmental Non-Profit Organizations.
Appliance Standards Awareness Project	ASAP	Efficiency Organization.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[5]

III. General Discussion

EPCA defines the class of GSLs as including GSILs, CFLs, general service LED and OLED lamps, and any other lamps that DOE determines are used to satisfy lighting applications traditionally served by GSILs; however, as specified by EPCA, GSLs do not include any lighting application or bulb shape that under 42 U.S.C. 6291(30)(D)(ii) is not included in the ''general service incandescent lamp'' definition, or any general service fluorescent lamp or incandescent reflector lamp. 42 U.S.C. 6291(30)(BB).

EPCA defines a GSIL generally as a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts. 42 U.S.C. 6291(30)(D)(i). This definition does not apply, however, to 22 lamp types.[6] 42 U.S.C. 6291(30)(D)(ii).

In the January 2017 Final Rules, DOE defined GSL to mean a lamp that had an ANSI base; was able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps, or was able to operate at any voltage for non-integrated lamps; had an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; was not a light fixture; was not an LED downlight retrofit kit; and was used in general lighting applications. 82 FR 7276, 7312. General service lamps included, but were not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-emitting diode lamps. 82 FR 7276, 7321.

Further in the January 2017 Final Rules, DOE defined GSLs to not include: (1) Appliance lamps; (2) Black light lamps; (3) Bug lamps; (4) Colored lamps; (5) G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002; (6) General service fluorescent lamps; (7) High intensity

[5] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop definitions for general service lamps. (Docket No. EERE–2021–BT–STD–0012, which is maintained at *www.regulations.gov*). The references are arranged as follows: (Commenter name, comment docket ID number at page of that document).

[6] These are: An appliance lamp; a black light lamp; a bug lamp; a colored lamp; an infrared lamp; a left-hand thread lamp; a marine lamp; a marine signal service lamp; a mine service lamp; a plant light lamp; a reflector lamp; a rough service lamp; a shatter-resistant lamp (including a shatter-proof lamp and a shatter-protected lamp); a sign service lamp; a silver bowl lamp; a showcase lamp; a three-way incandescent lamp; traffic signal lamp; a vibration service lamp; a G shape lamp (as defined in ANSI C78.20 and ANSI C79.1–2002) with a diameter of 5 inches or more; a T shape lamp (as defined in ANSI C78.20 and ANSI C79.1–2002) and that uses not more than 40 watts or has a length of more than 10 inches; and a B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp (as defined in ANSI C79.1–2002 and ANSI C78.20) of 40 watts or less. 42 U.S.C. 6291(30)(D)(ii).

discharge lamps; (8) Infrared lamps; (9) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases; (10) Lamps that have a wedge base or prefocus base; (11) Left-hand thread lamps; (12) Marine lamps; (13) Marine signal service lamps; (14) Mine service lamps; (15) MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002, operate at 12 volts, and have a lumen output greater than or equal to 800; (16) Other fluorescent lamps; (17) Plant light lamps; (18) R20 short lamps; (19) Reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases; (20) S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002; (21) Sign service lamps; (22) Silver bowl lamps; (23) Showcase lamps; (24) Specialty MR lamps; (25) T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002, nominal overall length less than 12 inches, and that are not compact fluorescent lamps; and (26) Traffic signal lamps. *Id.;* 82 FR 7322, 7333.

The January 2017 Final Rules defined GSIL to discontinue the exemptions for rough service lamps; shatter-resistant lamps; three-way incandescent lamps; vibration service lamps; reflector lamps; T-shape lamps of 40 W or less or length of 10 inches or more; and B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps of 40 W or less. 82 FR 7276, 7291.

As noted in the September 2019 Withdrawal Rule, these definitions were subsequently withdrawn (see section II.D of this document). In the August 2021 NOPR, DOE proposed to amend the definitions of *general service lamp* and *general service incandescent lamp.* DOE proposed to define a general service lamp as a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps (as defined in this section), or is able to operate at any voltage for non-integrated lamps (as defined in this section); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps included, but were not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light emitting diode lamps. General service lamps did not include:

(1) Appliance lamps;
(2) Black light lamps;
(3) Bug lamps;
(4) Colored lamps;
(5) G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3);
(6) General service fluorescent lamps;
(7) High intensity discharge lamps;
(8) Infrared lamps;
(9) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases;
(10) Lamps that have a wedge base or prefocus base;
(11) Left-hand thread lamps;
(12) Marine lamps;
(13) Marine signal service lamps;
(14) Mine service lamps;
(15) MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3), operate at 12 volts, and have a lumen output greater than or equal to 800;
(16) Other fluorescent lamps;
(17) Plant light lamps;
(18) R20 short lamps;
(19) Reflector lamps (as defined in this section) that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3) and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;
(20) S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3);
(21) Sign service lamps;
(22) Silver bowl lamps;
(23) Showcase lamps;
(24) Specialty MR lamps;
(25) T-shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3), nominal overall length less than 12 inches, and that are not compact fluorescent lamps (as defined in this section);
(26) Traffic signal lamps.

See 86 FR 46611, 46624–46625.

Similarly, DOE proposed to define a general service incandescent lamp as a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however, this definition did not apply to the following incandescent lamps—

(1) An appliance lamp;
(2) A black light lamp;
(3) A bug lamp;
(4) A colored lamp;
(5) A G shape lamp with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see 10 CFR 430.3);
(6) An infrared lamp;
(7) A left-hand thread lamp;
(8) A marine lamp;
(9) A marine signal service lamp;
(10) A mine service lamp;
(11) A plant light lamp;
(12) An R20 short lamp;
(13) A sign service lamp;
(14) A silver bowl lamp;
(15) A showcase lamp; and
(16) A traffic signal lamp.

See 86 FR 46611, 46624.

The proposed definitions of GSL and GSIL in the August 2021 NOPR were the same as those specified in the January 2017 Final Rules (*i.e.,* the January 2017 Definitions). For the definition of GSL, in the August 2021 NOPR, DOE proposed additional detail to the statutory definition by specifying the base type, lumens, and voltages of GSLs. DOE also proposed to remove the exemptions for certain incandescent lamps that are used to satisfy lighting applications traditionally served by GSILs and include those lamps in the definition of GSIL and GSL. DOE preliminarily determined these are lamps that can serve in general lighting applications and provide an interior or exterior area with overall illumination. DOE explained that it considers the term ''overall illumination'' to be similar in meaning to the term ''general lighting'' as defined in the industry standard ANSI/IES RP–16–10, which states that ''general lighting'' means lighting designed to provide a substantially uniform level of illuminance throughout an area, exclusive of any provision for special local requirements. 86 FR 46611, 46616.

As proposed in the August 2021 NOPR, the GSL and GSIL definitions explicitly include not only A-shaped or pear-shaped light bulbs but also the smaller, decorative shaped light bulbs resembling a candle, bullet or globe and often used in chandeliers, desk lamps,

ornamental wall lights, etc. Additionally, the proposed definitions include reflector shaped light bulbs that have a cone-like shape with an inner reflective coating that directs light and are often used in recessed light fixtures (*e.g.,* lights within the ceiling). Based on estimates from DOE's 2015 Lighting Market Characterization Report, the proposed definitions increase the number of lamps defined as GSL from 3.8 billion lamps to 5.8 billion lamps.[7]

The following discussion addresses issues raised by commenters on the proposal in the August 2021 NOPR to adopt the aforementioned definitions of GSL and GSIL as set forth in the January 2017 Final Rules. In general, the NPCC, NASEO, NYSERDA, the AGs, State of Washington DOC, CEC, Joint Comment, CA IOUs, ASAP, and SC, NRDC, and EJ all stated support for the proposed GSL definitions; while NEMA, GE Lighting, and Lutron suggested changes to the proposed definitions. (NPCC, No. 5 at p. 2; NASEO, No. 8 at p. 1; NYSERDA, No. 10 at p. 1; AGs, No. 11 at pp. 1–2; State of Washington DOC, No. 13 at pp. 1–2; CEC, No. 15 at pp. 2–3; Joint Comment, No. 16 at p. 1; CA IOUs, No. 17 at p. 1; ASAP, No. 19 at pp. 1–2; SC, NRDC, and EJ, No. 18 at pp. 1–2; NEMA, No. 9 at pp. 7–9; GE Lighting, No. 14 at pp. 3–4; Lutron, No. 12 at pp. 3–5).

A. September 2019 Withdrawal Rule

DOE received several comments on the August 2021 NOPR regarding the September 2019 Withdrawal Rule. This rule withdrew the GSL and GSIL definitions established by the January 2017 Final Rules. The CEC stated that DOE's purported withdrawal of the January 2017 Final Rules was unlawful and unlawfully amended the minimum standard for many lamp types to their previous less efficient levels. The CEC stated that in its effort to undo the January 2017 Final Rules, DOE failed to provide sufficient reasoning for its changed legal interpretation and failed to give statutory meaning to EPCA's GSL and GSIL provisions. (CEC, No. 15 at pp. 2–3)

The SC, NRDC, and EJ asserted that the fundamental flaw of the September 2019 Withdrawal Rule, which they believe provides grounds for its immediate revocation, is its violation of EPCA's anti-backsliding provision. The SC, NRDC, and EJ stated that had DOE not issued the September 2019 Withdrawal Rule, the standard that would have applied to the lamps exempted in that rule would have been 45 lm/W on January 1, 2020. Because DOE issued the September 2019 Withdrawal Rule, SC, NRDC, and EJ asserted that the standard applicable to those lamps is either (1) no standard at all, or (2) a standard requiring a lower level of energy efficiency. The SC, NRDC, and EJ stated that DOE made a policy judgment in a separate rulemaking, applicable to this scenario, that ''nominally characterizing a regulatory change in the energy conservation standards applicable to a covered product as something other than an amendment'' is inconsistent with EPCA.[8] The AGs referenced and attached their May 3, 2019 comments written in response to the February 2019 Withdrawal NOPR, in which they stated that DOE's planned action to repeal the January 2017 Definitions would be unlawful; violated EPCA's anti-backsliding provision (see 42 U.S.C. 6295(o)(1)); and lacked any statutory basis for exempting the bulbs at issue from existing efficiency standards. The AGs stated that a petition for review of the September 2019 Withdrawal Rule was filed (*New York* v. *DOE,* No. 19–3652 (2d Cir. 2019)) in 2019, which is now in abeyance pending DOE's current reconsideration of the withdrawal under Executive Order 13990. (AGs, No. 11 at pp. 1–2; CEC, No. 15 at pp. 2–3; SC, NRDC, and EJ, No. 18 at pp. 1–2)

Additionally, the AGs, CEC, and SC, NRDC, and EJ agreed with DOE's tentative conclusion that DOE, in the September 2019 Withdrawal Rule, incorrectly interpreted that it could not exercise its authority to remove exemptions for certain incandescent lamps that are not used in general lighting applications. The AGs stated that neither EPCA's separate regulatory process under 42 U.S.C. 6295(l)(4) nor its exclusions under 42 U.S.C. 6291(30)(D)(ii)(XI) and 42 U.S.C. 6291(30)(BB)(ii)(II) for certain lamps precludes DOE from defining them as GSLs. (AGs, No. 11 at pp. 1–2) The NPCC and CEC added that under EPCA, DOE has the authority to adjust the scope of GSLs and determine whether exemptions for certain incandescent lamps should be discontinued or maintained. (NPCC, No. 5 at p. 2; CEC, No. 15 at pp. 2–3)

EPCA directs DOE to amend the statutory definitions of GSL and GSIL by regulation to achieve the energy savings for general lighting that Congress intended in EPCA generally and EISA specifically. 42 U.S.C. 6295(i)(6)(A)(i)(II) and 42 U.S.C. 6291(30)(BB)(i)(IV). By withdrawing the expanded definitions of GSL and GSIL in the September 2019 Withdrawal Rule, DOE failed to give meaningful effect to this statutory direction. As noted in the August 2021 NOPR, DOE was wrong to conclude in the September 2019 Withdrawal Rule that ''maintaining the existing statutory exemptions for the 22 categories of lamps excluded from the definition of GSL is the best reading of the statute.'' 84 FR 46666, 86 FR 46617. DOE's authority under 42 U.S.C. 6291(30)(BB)(i)(IV) to include within the definition of GSL ''any other lamps that [it] determines are used to satisfy lighting applications traditionally served by general service incandescent lamps'' empowers the agency to include categories of lamps that would otherwise be excluded under 42 U.S.C. 6291(30)(BB)(ii). And DOE's authority under 42 U.S.C. 6295(i)(6)(A)(i)(II) empowers the agency to discontinue any of the exemptions from the definition of GSIL set out in 42 U.S.C. 6291(30)(D)(ii). DOE's basis for discontinuing certain of the exemptions as discussed in the August 2021 NOPR and presented in the January 2017 Final Rules is the best implementation of the statute because it properly considers the statute as a whole and considers whether such lamps have the potential for use in general lighting applications traditionally served by GSILs. This final rule adopts the definitions established in the January 2017 Final Rules and as proposed in the August 2021 NOPR because they best align with EPCA's goals for increasing the energy efficiency of covered products through the establishment and amendment of energy conservation standards and promoting conservation measures when feasible. 42 U.S.C. 6291 *et seq.,* as amended.

B. Reflector Lamps

As discussed, in the August 2021 NOPR, DOE proposed to include IRLs within the definition of *general service lamp,* except those reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3) and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases. 86 FR 46611, 46620.

Additionally, in the August 2021 NOPR, DOE reviewed its position in the September 2019 Withdrawal Rule that EPCA precludes consideration of the exemption for IRLs because they were exempted twice from the statute. In the NOPR, DOE proposed to amend the

[7] Navigant Consulting, Inc. 2015 U.S. Lighting Market Characterization (No. DOE/EE–1719). U.S. Department of Energy, Washington, DC.

[8] *See* Notice of Proposed Rulemaking for Residential Dishwashers, Residential Clothes Washers, and Consumer Clothes Dryers published August 11, 2021. 86 FR 43970.

definitions of GSIL and GSL to discontinue the exemptions for these products. 86 FR 46611, 46620. In response, NEMA suggested that DOE modify the proposed GSL definition to exclude IRLs from the GSL definition. NEMA and GE Lighting stated that IRLs are already covered under existing regulations for IRLs and were never intended to be regulated as GSLs according to EISA, where they are addressed in a separate regulatory section. Additionally, NEMA stated separation of IRLs from GSLs would avoid confusion and make a phased-in regulation more understandable. NEMA requested that DOE clarify how IRLs that are included in the proposed GSL definition and are also already regulated separately under existing regulations will be treated from an enforcement standpoint. NEMA stated that in the absence of clarity, manufacturers must assume that such products that meet the existing definition of IRLs and also meet the current standard for those products must be certified to DOE according to existing law and continue to be made and sold. (NEMA, No. 9 at pp. 6–9; NEMA, No. 9 at p. 10; GE Lighting, No. 14 at p. 3)

The September 2019 Withdrawal Rule concluded that because IRLs were twice excluded from the statute, once from the GSIL definition in 42 U.S.C. 6291(30)(D)(ii)(XI) and once from the GSL definition in 42 U.S.C. 6291(30)(BB)(ii)(II), that means Congress did not want the Secretary to include IRLs within the definition of GSL. 84 FR 46661, 46666. DOE acknowledges that the statute exempts ''reflector lamp'' from the definition of GSIL (42 U.S.C. 6291(30)(D)(ii)(XI)) and ''incandescent reflector lamp'' from the definition of GSL (42 U.S.C. 6291(30)(BB)(ii)(II)). However, on reconsideration, DOE does not read the two statutory exemption provisions as an indication that such lamps were not to be evaluated for coverage under the GSIL and GSL definitions. With respect to IRLs, the best reading of the statute as a whole is that 42 U.S.C. 6291(30)(BB)(i)(IV) and 42 U.S.C. 6295(i)(6)(A)(i)(II) authorize DOE to determine whether to include IRLs within the definition of GSIL and GSL. Section 6295(i)(6)(A)(i)(II) grants DOE authority to determine whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' As discussed previously, in footnote 3, these ''exemptions'' are set out in 42 U.S.C. 6291(30)(D)(ii), and include IRLs among other lamps. As such, 42 U.S.C. 6295(i)(6)(A)(i) provides DOE with authority to consider Congress' initial exemption of those lamp types from the definition of GSIL, to determine whether those exemptions should be maintained or rescinded. Moreover, all of the lamp types that Congress initially exempted from being considered GSILs in 42 U.S.C. 6291(30)(D)(ii) were likewise initially exempted from being considered GSLs in 42 U.S.C. 6291(30)(BB)(ii). When DOE discontinues an exemption from the definition of GSIL through 42 U.S.C. 6295(i)(6)(A)(i), the lamps that newly qualify as GSILs also become GSLs—because all GSILs are GSLs under 42 U.S.C. 6291(30)(BB)(i)(I), notwithstanding the exclusion of certain lamp types from the definition of GSL in 42 U.S.C. 6291(30)(BB)(ii). (Lamp types statutorily exempted from the definition of GSIL and GSL under 42 U.S.C. 6291(30)(D)(ii) and 42 U.S.C. 6291(30)(BB)(ii), and for which DOE did not discontinue such exemption, remain exempted.) Similarly, under 42 U.S.C. 6291(30)(BB)(i)(IV), DOE has the power to bring within the definition of GSL ''any other lamps that the Secretary determines are used to satisfy lighting applications traditionally served by general service incandescent lamps.'' That authority is not limited by the exclusions in 42 U.S.C. 6291(30)(BB)(ii). Rather, DOE has the power to bring within the definition of GSL any lamps excluded by 42 U.S.C. 6291(30)(BB)(ii), if it determines that they are used to satisfy lighting applications traditionally served by general service incandescent lamps. DOE therefore has the power to bring IRLs within the definition of GSIL and GSL, notwithstanding the statutory exclusions in 42 U.S.C. 6291(30)(D)(ii) and 42 U.S.C. 6291(30)(BB)(ii). DOE concludes that the discontinuation of the exemption for IRLs is warranted, for the reasons discussed in the second of the January 2017 Final Rules, published at 82 FR 7322. In that rule, DOE determined that medium screw base reflector lamps that are incandescent and do not meet the definition of IRL as well as lamps that are IRLs, separately, had high annual unit sales indicating they are likely to be used in general lighting applications. Further, because these lamps provide overall illumination, they could be used as direct replacements for GSILs. DOE also indicated there was a high potential for lamp switching to IRLs and medium screw base reflector lamps that are incandescent due to the fact they are used in general lighting applications like others GSILs and GSLs. Lastly, as shown in Table III.1 of the second January 2017 final rule, IRLs have annual sales that are several times the sales of the largest-volume lamp category among those exemptions that DOE is discontinuing, all of which are lamps used in general lighting applications. 82 FR 7276, 7293; 82 FR 7322, 7329–7330. For these reasons, in this final rule, DOE includes IRLs in the definition of GSL and GSIL.

DOE acknowledges that IRLs are currently subject to standards. 10 CFR 430.32(n)(6) and (7). This rule is not specifying standards for GSLs. To the extent that DOE were to establish energy conservation standards for GSLs, DOE would clearly indicate the applicable standard and compliance requirements for the affected lamps. Further, DOE notes that GSILs and medium base CFLs are also already covered under existing regulations and yet are explicitly included as GSLs under EPCA.

NEMA commented that separate regulations for IRLs and GSLs will allow consideration for the unique efficiency and light distribution capabilities of reflector and omnidirectional GSLs. GE Lighting stated that IRLs are not general lighting and are used to highlight specific objects or target areas in a room, and therefore, require a unique technical analysis. (NEMA, No. 9 at pp. 6–7; NEMA, No. 9 at p. 10; GE Lighting, No. 14 at p. 3)

In the January 2017 Final Rules, DOE found that IRLs are widely used for general illumination just as GSILs are used. 82 FR 7322, 7325. In this final rule, DOE finds there has been no change in the market that leads to a different conclusion in this final rule. Further, when determining standards for a product, DOE divides covered products into classes by: (a) The type of energy used; (b) the capacity of the product; or (c) other performance-related features that justify different standard levels, considering the consumer utility of the feature and other relevant factors. (42 U.S.C. 6295(q)) Because DOE considers impact on both efficacy and consumer utility when establishing product classes, reflector and omnidirectional GSLs could be analyzed for standards separately, if warranted.

C. Consumer Choice, Health Impacts

Some private citizens stated that the GSL definitions proposed in the August 2021 NOPR infringe on consumer choice by regulating incandescent bulbs under GSLs and effectively removing them from the marketplace. (Anonymous, No. 2 at p. 1; Anonymous, No. 3 at p. 1; Anonymous, No. 4 at p. 1)

In the August 2021 NOPR, DOE proposed that if the design

characteristics of lamps for a given application are such that non-incandescent lamps cannot be made with the same characteristics (*i.e.,* form factor and light output), such lamps should not be included as ''other lamps'' in its definition of GSL. *See* 86 FR 46616; *see also* 82 FR 7276, 7301. Hence, in this final rule, incandescent lamps that are included as GSLs have or can have more efficient, non-incandescent replacements with the same form factor and light output. DOE has confirmed that all lamp types included in the GSL definition have the same characteristics in the non-incandescent versions as offered in the incandescent versions.

Regarding T-Shape, B, BA, F, G16–1/2, G25, G30, S and M–14 lamps (''decorative lamps''), NEMA estimates total market volume at 950 million installed lamps; and 520 million out of 665 million on mostly switch-controlled sockets have already been converted to LED technology. NEMA stated that regulations would force homeowners with the remaining 285 million incandescent decorative lamps on dimmers to switch to LED technology that is often incompatible with the installed dimmers. NEMA stated that for a dining room fixture an LED-compatible dimmer could cost approximately $20 to $80, plus $100 to $200 (depending on location) for an electrician to install. NEMA stated that a mid-cost $30 dimmer with a lower cost electrician ($100) would have a payback in 30 years, and a high-cost dimmer ($80) with a high-cost electrician ($200) would have a payback in 65 years. NEMA stated that regulating candelabra base lamps used on LED-incompatible dimmers is not economically feasible for homeowners; rather, the market will convert to LED over time without regulation due to homeowners continuing to replace dimmers by choice. (NEMA, No. 20 at pp. 3–4)

Regarding dimming, not all incandescent/halogen dimmers (*i.e.,* phase-cut control dimmers) are incompatible with LED technology. NEMA's SSL 7A, which provides basic requirements for phase-cut dimming of LED light sources, includes a list of forward phase-cut dimmers and scenarios in which they can be compatible with LED technology (*e.g.,* up to 125 W LED load). NEMA's comment indicates that almost 80 percent of the lamps on switch-controlled sockets have already been converted to LED technology without a significant negative market reaction. Thus, the extensive use of dimmer technology needed to support the modified GSL definition in this final rule indicates that it is readily available and economically feasible for consumers.

Further, this final rule defines only the scope of GSLs and does not set energy efficiency standards for GSLs. When DOE evaluates a future energy efficiency standard for GSLs it will determine whether a standard is economically justified based on several factors, including consumer impacts and commenters' concerns relating to any asserted lessening of the utility or the performance of newly covered GSILs likely to result from the imposition of the standard. 42 U.S.C. 6295(o)(2)(B)(i)(II)–(IV).

A private citizen stated that for some people LED lamps may have a negative effect on eyesight and thus wished to continue purchasing incandescent bulbs. (Anonymous, No. 4 at p. 1) A second private citizen stated that LED bulbs may affect those with light sensitivity disabilities and under Title 1 of the American Disabilities Act (''ADA'') reasonable accommodation must be made for those that have disabilities and are light sensitive. The citizen stated that, for example, people with epilepsy need to use incandescent lights. The citizen stated that a government project is required by federal ADA law to ensure that those with light sensitivity disabilities are not harmed by artificial lighting used in the project. The citizen stated that the United Kingdom makes accommodations for those that have a disability to use incandescent bulbs. Finally, the citizen stated that Title II of the ADA states DOE has a responsibility to consult with the disabled community prior to changing lighting standards and that reasonable accommodation be made to purchase incandescent bulbs for medical reasons. (Anonymous, No. 6 at p. 1)

Though these public comments do not include quantitative evidence of specific alleged changes to performance characteristics relevant to consumer choice or health, DOE has considered these public comments. DOE has also considered the potential for health benefits of emissions reductions from reducing energy use by the covered products. DOE maintains that the final rule's definitional changes appropriately promote EPCA's goals for increasing the energy efficiency of covered products through the establishment and amendment of energy conservation standards and promoting conservation measures when feasible. 42 U.S.C. 6291 *et seq.,* as amended. As stated above, DOE assesses possible impacts to consumers, utility, and performance during the separate evaluation of economic justification for setting energy conservation standards. Additionally, DOE notes that the ADA does not apply to DOE for purposes of this rule, as the ADA applies only to private employers and not Federal agencies. Individuals wishing to file complaints under the ADA can visit *www.ada.gov.*

D. Potential Revisions to the Proposed Definitions

1. Lumens

NYSERDA and the CEC recommended that DOE revise the GSL definition proposed in the August 2021 NOPR to include lower lumen products between 150 and 310 lumens to include lamps offered as 25-watt (''W'') equivalents. ASAP, the CA IOUs, and NYSERDA stated that this would align with California's state-regulated LED lamps which include E12 base lamps greater or equal to 150 lumens and E26, E17, GU24 base lamps greater or equal to 200 lumens. ASAP stated that these low-lumen lamps are often used in multiples in a single light fixture to provide general illumination. As an example, NYSERDA stated a fixture with eight candelabra bulbs consumes 10 times more energy than a single 100 W equivalent LED bulb. The CEC stated that low-lumen lamps are typically used to satisfy lighting applications traditionally served by GSILs (*e.g.,* night lights) and that one-quarter of California homes have at least one low-lumen lamp. The CEC also stated that there are a sufficient number of low-lumen lamps on the market that would meet the 45 lm/W standard, citing its 2018 analysis which found 571 ENERGY STAR® certified LED lamps with low lumens and efficacy far above 45 lm/W. The CA IOUs added that a cluster of low-lumen incandescent lamps remains in the retail space and there is no technical reason not to cover the products in the GSL definition. The CEC added that low-lumen lamps included in the GSL definition would be limited to the base types specified in the definition, excluding other low-lumen base types and specialty lamps. (NYSERDA, No. 10 at p. 2; CEC, No. 15 at pp. 3–4; ASAP, Public Meeting Transcript, No. 7 at pp. 13–14; CA IOUs, Public Meeting Transcript, No. 7 at pp. 14–15)

Westinghouse commented that many of the low-lumen lamps described by ASAP and the CA IOUs are not used in general service applications, but specialty signs and indicators. Westinghouse expressed concern that inclusion of low-lumen lamps of any American National Standards Institute (''ANSI'') base could also include

specialty products. (Westinghouse, Public Meeting Transcript, No. 7 at pp. 15–16) GE Lighting stated that lamps below 310 lumens are not 40 W, but instead between 15 and 25 W, and 40 W lamps are typically in the 350 to 450 lumen range. GE Lighting added that these lamps have very low market share, are used in niche applications, and use little wattage. (GE Lighting, Public meeting Transcript, No. 7 at pp. 16–17)

In the August 2021 NOPR, DOE tentatively determined, based on the reasoning presented in the January 2017 Final Rules, that lamps that satisfy the same applications traditionally served by GSILs are ones that provide overall illumination. 86 FR 46611, 46616. In the January 2017 Final Rules, DOE determined that the minimum lumen output of lamps that provide overall illumination should be 310 lumens. DOE acknowledged that some lamps with lumen outputs less than 310 lumens can be marketed as 25 W equivalents. However, there are no Federal guidelines concerning equivalency claims of lamps and even when such guidelines exist there is a variety in lumens that constitute a 25 W equivalent. 82 FR 7276, 7305–7306. DOE finds there has been no change in the market that would lead DOE to reach a different conclusion in this final rule and therefore is adopting a GSL definition with minimum lumens as 310 lumens.

2. Base Type and Voltage

NEMA and GE Lighting recommended that DOE make modifications to the base type and voltage in the proposed GSL definition to provide clarity and to avoid causing specialty and niche products that have unique performance features to become unavailable in the market. GE Lighting stated that the proposed definition goes beyond the original EISA 2007 definition regulating household A-line incandescent 40, 60, 75 and 100 W lamps, or potential replacements for these lamps. (NEMA, No. 9 at p. 8; GE Lighting, No. 14 at pp. 3–4)

NEMA stated that DOE's proposal that GSLs have an ANSI base is so overly broad so as to create confusion in the market and result in DOE unintentionally making specialty lamp types with unique performance features unavailable. NEMA recommended that DOE modify the definition to specify GSLs have an E26 medium screw base, E17 intermediate base, E12 candelabra base, E11 mini candelabra base, E39 or EX39 mogul base, or G5.3, GU10, or GU24 base. (NEMA, No. 9 at p. 8)

Second, NEMA stated that DOE's proposal that GSLs that are non-integrated lamps that operate at any voltage is unnecessarily broad. NEMA stated that the common residential and commercial building mains voltages are 110/120, 208, and 277 volts (''V''). NEMA recommended that DOE modify the definition to specify that GSLs that are non-integrated lamps be able to operate between 100 to 277 V. (NEMA, No. 9 at p. 8)

GE Lighting recommended two alternative modifications to the base and voltage: (1) Limit the base type to medium screw bases and operation between 120 and 130 V; or (2) limit the base type to medium, candelabra, and intermediate screw bases and operation between 120 and 130 V. GE Lighting stated that medium screw base, candelabra base and intermediate screw base lamps that operate between 120 and 130 V and provide omnidirectional light distribution would cover 99 percent of the GSLs used in a home (excluding reflector lamps) according to the 2015 DOE Lighting Market Characterization Report and, therefore, achieve over 99 percent of the potential energy savings. GE Lighting also stated that using specific base types and voltages used in a home would be easy to understand. (GE Lighting, No. 14 at pp. 3–4)

In the August 2021 NOPR, DOE tentatively determined that lamps that satisfy the same applications traditionally served by GSILs are ones that provide overall illumination. 86 FR 46611, 46616. Based on the findings of the January 2017 Final Rules that lamps with an ANSI base provide overall illumination, DOE proposed in the August 2021 NOPR to define GSLs to include lamps with an ANSI base. 86 FR 46611, 46619. In the January 2017 Final Rules, DOE also identified lamps with ANSI bases that were associated with certain incandescent/halogen lamps without more efficient, equivalent replacements and concluded that those lamps should be exempted. DOE concluded that the unavailability of non-incandescent substitutes for a given lamp suggests that lamp is not being used for traditional GSIL applications. 82 FR 7276, 7301. As such, DOE exempted: (1) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases; (2) lamps that have a wedge base or prefocus base; and (3) reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases. 82 FR 7276, 7304. Hence, based on these findings of the January 2017 Final Rules, in the August 2021 NOPR, DOE proposed exempting the aforementioned lamps because they may not have more efficient, equivalent replacements available if a future GSL standard is adopted. DOE's findings of the January 2017 Final Rules found that many lamps with medium, candelabra, and intermediate screw bases, operating between 120 V and 130 V could provide overall illumination and therefore, could not use these criteria as suggested by GE. Further, ANSI bases are well defined in the industry standard ANSI C81.61, ''Electric Lamp Bases—Specifications for Bases (Caps) For Electric Lamps.'' DOE finds that the GSL definition as proposed in the August 2021 NOPR is easy to understand when it specifies that lamps must have ANSI bases and exempts certain lamps using an ANSI base designation. In this final rule, DOE is adopting the GSL definition as proposed, which defines such lamps as having ANSI bases.

In the January 2017 Final Rules, DOE reviewed available product offerings to determine whether lamps of all operating voltages are used in general lighting applications. DOE determined that integrated lamps able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts provide overall illumination. DOE made this determination by reviewing product offerings and identifying voltages associated with specialty lamps and ensuring those are not included in the ranges of a GSL. DOE found that the operating voltage of non-integrated lamps did not correlate to use in specialty applications. 82 FR 7276, 7306. DOE finds there has been no change in the market regarding lamp voltages that would lead DOE to reach a different conclusion in this final rule. Hence, in this final rule, DOE is adopting, as proposed in the August 2021 NOPR, the GSL definition established in the January 2017 Rules that defines integrated lamps in voltage ranges of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts.

3. Color Tunable Lamps

Lutron stated that when considering the scope of the GSL definition, DOE should take into consideration the impact of including advanced technologies, specifically full color tunable lamps. Lutron stated full color tunable lamps can change between emitting high quality white light typically used in general lighting applications and colored lighting typically used for decorative purposes. Lutron stated luminous flux measures the perceived intensity of light,

weighted by the human eye sensitivity curve to differing wavelengths (colors) of light, V(λ). Hence, lamps outputting colors of light to which the human eye is not as sensitive (*i.e.,* color others than white) will always appear to be less efficacious than a comparable source outputting white light. Lutron stated that full color tunable lamps when operated in colors other than white will therefore be measured as having a lower lumen output. Lutron noted that the current DOE test procedure requires lamps to be tested at the highest input power for efficacy, CRI, and other metrics. Lutron stated that although it is often the case that one or more white light settings are among the set of highest input power settings, this cannot be assumed. Lutron also stated innovation in phosphor-converted LEDs may enable efficacy gains when operating at white light settings but at a lower input power. Lutron asserted that the current DOE test procedure of testing at the highest input power would disincentivize this kind of innovation. (Lutron, No. 12 at p. 3)

Lutron proposed two possible solutions to the problem it identified. The first option Lutron proposed was to exclude ''full color tunable lamps'' from the definition of GSL. Lutron stated that the reason for the exclusion would align with the reasons for excluding colored lamps. Further, Lutron stated that full color tunable lamps are not yet mainstream products and when operated in deeply saturated colors are often used for short-term events or in decorative applications. Lutron recommended the following definition for the exempt lamp type: ''Full color tunable lamp means a lamp capable of emitting highly saturated light of varying hues, as well as white light, for example by varying the relative intensity of individual emitters.'' (Lutron, No. 12 at pp. 3–4)

Alternatively, Lutron proposed DOE open a rulemaking to revise the test procedure to appropriately evaluate full color tunable lamps. Instead of testing at maximum input power, Lutron recommended testing tunable products in their default mode of operation, which is consistent with other design standards.[9] Lutron added that DOE would then need to open a rulemaking to revise the standards for GSLs to accommodate for multiple emitters, each operating at a different efficacy, in full color tunable lamps. Lutron stated that full color tunable lamps should ultimately be considered by DOE as a separate product class with a separate standard. Lutron stated this option should still include defining the term ''full color tunable lamp.'' (Lutron, No. 12 at pp. 3–4)

Lutron commented that, of the two solutions, it would be easier to exempt full color tunable lamps and allow the focus of the rulemaking to return to traditional lighting technology. (Lutron, No. 12 at pp. 3–4)

EPCA directs DOE to include as GSLs, lamps which are used to satisfy lighting applications traditionally served by GSILs. 42 U.S.C. 6291(30)(BB)(i)(IV). In the January 2017 Final Rules, DOE determined that lamps that satisfy the same applications traditionally served by GSILs are ones that provide an interior or exterior area with overall illumination. 82 FR 7276, 7306. Because colored lamps do not provide overall illumination, in the January 2017 Final Rules, DOE maintained the exemption of colored lamps specified in the GSIL definition and applied it to the GSL definition. 82 FR 7276, 7302, 7312. Colored lamps have correlated color temperatures (CCTs) or color rendering indexes (CRIs) that do not result in white light, and therefore do not satisfy lighting applications traditionally served by GSILs (*i.e.,* colored lamps do not provide overall illumination). DOE reaffirmed this position in the August 2021 NOPR by proposing to exclude colored lamps from the definition of GSIL and GSL. 86 FR 4611, 46616, 46625. DOE understands that full color tunable lamps can be operated to provide overall illumination as well as colored light. At the setting where the full color tunable lamp is producing colored light, the CCT or CRI will be such that it does not result in white light. Accordingly, at a setting where the full color tunable lamp is not producing colored light, the CCT or CRI will be such that it does result in white light. Because consumers can choose to use them to provide overall illumination, exempting such lamps could result in manufacturers adding color tunability to avoid standards, *i.e.,* a potential loophole. Hence, DOE is not modifying the GSL definition proposed in the August 2021 NOPR to exempt full color tunable lamps. DOE will review the most appropriate method to test such lamps in its next review of the applicable lamp test procedure.

E. Market Share, Cost Savings, Energy Savings, and Emission Reductions

1. Market Share

DOE also received comments on the August 2021 NOPR relating to the market share of GSLs. The Joint Comment stated that while LEDs have gained an overall market share of about 60 percent,[10] the 40 percent of incandescent products are costing consumers. (Joint Comment, No. 16 at p. 2) NASEO and ASAP commented that consumers continue to purchase incandescent bulbs out of habit and because manufacturers promote them. (NASEO, No. 8 at p. 2; ASAP, No. 19 at p. 2) NYSERDA stated that results of a survey it conducted showed that nationally, of the overall lamp market 58 percent of A-lamps, 84 percent of reflector lamps, 50 percent of globe lamps, and 56 percent of candelabra lamps were LED lamps in 2020 and had increased from the previous year. NYSERDA stated LED lamps were widely available even in states that did not have utility energy efficiency lighting incentives. However, the NYSERDA survey indicated that while LED globe lamps grew by 2 percent in 2020 from the previous year, incandescent globe lamps grew by 5 percent. (NYSERDA, No. 10 at pp. 2–3)

The CA IOUs stated that implementation of the 45 lm/W backstop on lamps included in the January 2017 Definitions will significantly increase the number of products impacted and decrease the potential of an increase in sales volume of non-GSL incandescent lamps. (CA IOUs, No. 17 at p. 3) The NPCC stated that ''specialty'' lamps for which the exemptions are being discontinued (*i.e.,* reflector bulbs used in recessed and track lighting, candle-shaped bulbs used in wall sconces and decorative light fixtures, globe-shaped bulbs often installed in bathrooms, pear-shaped bulbs, etc.) represent a significant portion of the Pacific Northwest's energy efficiency potential, as there are over 250 million of these bulbs in the region. The NPCC stated that LED lamps provide equal or better service at a much lower energy consumption rate and higher durability. (NPCC, No. 5 at pp. 1–2) The CA IOUs stated that when incandescent light bulbs leave the market, any economic harm to the lighting industry will be far outweighed by the energy and environmental savings. (CA IOUs, No. 17 at p. 2)

2. Consumer Costs, Energy Savings, Emission Reductions

DOE received several comments on the benefits of amending the definitions of GSL and GSIL as proposed in the August 2021 NOPR. The State of Washington DOC stated that although

[9] EU ecodesign regulation for light sources (*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R2020*) and the Global Lighting Association's Regulatory Guidelines for an Effective Transition to Energy Efficient Lighting.

[10] The Joint Comment referenced market research from Apex Analytics.

Washington already has a 45 lm/W efficacy standard in place, the proposed DOE action will strengthen enforcement and improve compliance in Washington, as well as avoid excess electricity consumption in other Western states, especially those without a state-level standard for GSLs as the Western electricity grid is very interconnected. (State of Washington DOC, No. 13 at pp. 1–2) The SC, NRDC, and EJ stated that the two-year delay in reinstatement of the January 2017 Definitions and application of the 45 lm/W backstop has prevented gains in reducing air pollutant emissions associated with electricity generation and consumer benefits, in particular, for low-income families. (SC, NRDC, and EJ, No. 18 at p. 2) NASEO and the State of Washington DOC stated that adopting the proposed GSL definitions will deliver large cost savings for consumers and reductions in climate emissions and encouraged the two-step process of first, expanding the definition of GSL to include all common bulb types and second, implementing the 45 lm/W backstop standard. (NASEO, No. 8 at p. 1; State of Washington DOC, No. 13 at pp. 1–2)

DOE also received comments that quantified cost savings and emissions reductions from adopting the definitions as proposed in the August 2021 NOPR. The AGs stated that, if adopted, the proposed definitions would save billions of dollars in energy costs and avoidance of millions of metric tons of greenhouse gas emissions annually. (AGs, No. 11 at p. 1) NASEO, the Joint Comment, and ASAP stated that switching a single incandescent bulb to LED saves $40–$90 over 10 years. Therefore, a midpoint of $65 in savings for a typical 45 bulbs per household would result in average estimated savings of $3,000 over 10 years. (NASEO, No. 8 at pp. 1–2; Joint Comment, No. 16 at p. 2; ASAP, No. 19 at p. 2) NASEO added that according to ASAP, updated GSL standards could result in nationwide utility bill savings of $2.6 billion by 2035. (NASEO, No. 8 at p. 2) NYSERDA stated that the additional products included in the expanded GSL definition, with the exclusion of A-lamps, would result in $1–$1.4 billion of net present value. (NYSERDA, No. 10 at p. 2) The CEC added that adopting the expanded definitions plus enforcing the backstop of 45 lm/W would result in $3.4 billion in cost savings each year. (CEC, No. 15 at p. 2) The Joint Comment stated that each month of additional delay in implementing the 45 lm/W standard will result in $300 million in lost savings through higher electricity bills and $1.8 billion has already been spent by consumers on inefficient lighting costs since January 2021. (Joint Comment, No. 16 at pp. 1–2; ASAP, No. 19 at p. 2)

NASEO stated that according to ASAP, the proposed GSL definitions could avoid an annual 2.7 to 6.2 million metric tons (''MMT'') of carbon dioxide (''CO_2'') emissions by 2030. (NASEO, No. 8 at p. 2) NYSERDA stated that the additional products included in the expanded GSL definition, with the exclusion of A-lamps, would reduce emissions by 0.25 to 0.5 MMT of CO_2. (NYSERDA, No. 12 at p. 2) The CEC added that adopting the expanded definitions plus enforcing the backstop of 45 lm/W would result in 9.5 MMT of avoided CO_2 emissions each year. (CEC, No. 15 at p. 2) The Joint Comment and ASAP stated that each month of additional delay in implementing the January 1, 2020, backstop will result in the addition of 800,000 tons of CO_2 emissions. The Joint Comment stated that since the beginning of the new administration 4.8 million tons of CO_2 have been needlessly released. (Joint Comment, No. 16 at pp. 1–2; ASAP, No. 19 at p. 2)

DOE also received several comments regarding low-income consumers and adopting the January 2017 Definitions. NASEO and ASAP stated that lower income consumers lack easy access to retailers that sell affordable LED lamps and expanding the GSL definition would ensure access to a larger consumer base. (NASEO, No. 8 at p. 2; ASAP, No. 19 at p. 2) NYSERDA cited a study it commissioned which assessed the lighting market in New York state. The study showed that LED lamps appear to be less available in dense urban environments, as smaller businesses such as grocery, hardware, and general merchandise stores have the lowest availability of LED lamps, compared to big-box or national operations typically located outside urban city centers. NYSERDA stated that DOE's proposed rule can solve the resulting issue of inequitable access to LED lamps. (NYSERDA, No. 10 at pp. 3–4) Based on research in Michigan and New York, the Joint Comment also found that low-income consumers, particularly in urban areas, have less access to affordable LED lamps than other consumers because the stores they often shop at do not stock them or set prices high. The Joint Comment stated that the proposed GSL definition would ensure that all consumers have access to LED lamps regardless of distribution channel (*i.e.,* big box suburban stores, grocery stores, hardware stores, dollar stores, corner stores). The Joint Comment added that low-income consumers tend to have disproportionately higher energy bills and are typically renters of housing with inefficient pre-installed lightbulbs (*i.e.,* incandescent lamps or CFLs). The Joint Comment also stated that when the commercial and industrial sectors save on lighting costs, these energy savings can be passed on to consumers in the form of lower costs for goods and services and can be spent in other areas of our economy with greater multiplier effects. Furthermore, the Joint Comment stated that a 2019 Consumer Federation of America (''CFA'') survey found that two-thirds of respondents support Federal energy efficiency standards for light bulbs, citing energy savings and less frequent light bulb replacements as benefits. (Joint Comment, No. 16 at p. 2)

Although this final rule only defines the scope of GSLs and does not set energy efficiency standards for GSLs, DOE appreciates commenters' information regarding estimated impacts of the adoption of the proposed August 2021 definitions on the market, consumer costs, energy savings, and emissions reductions. DOE has also conducted an analysis of the impacts of expanding the definitions of GSL and GSIL if the statutory backstop requirement for GSLs comes into effect. This analysis shows consumers will save $2.2 billion in annualized reduced operating costs savings at a 7% discount rate, and $2.3 billion at a 3% discount rate, and reduce CO_2 emissions by 174 million metric tons from products shipped between 2022–2051. Please see III.H of this document for a discussion of this analysis.

F. State Preemption

NEMA requested that the GSL definition final rule specify in clear and unambiguous language that the federal definition of a product class preempts any existing or future State definition. (NEMA, No. 9 at p. 7)

In response, DOE notes that Federal energy conservation requirements generally supersede state laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) Absent limited exceptions, states generally are precluded from adopting energy conservation standards for covered products both before an energy conservation standard becomes effective, and after an energy conservation standard becomes effective. (42 U.S.C. 6297(b) and (c))

For energy conservation standards applicable to GSLs, EISA 2007 established additional preemption

provisions specific to California and Nevada. Namely, beginning January 1, 2018, no provision of law can preclude these states from adopting: (1) Standards established in a final DOE rule adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv); (2) the backstop requirement of 45 lm/W if no final rule was adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv); or (3) for the State of California, if a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), any California regulations related to ''these covered products'' adopted pursuant to state statute in effect as of the date of enactment of EISA 2007 (*i.e.,* December 19, 2007). (42 U.S.C. 6295(i)(6)(A)(vi))

G. Effective Date

1. GSL Definitions Effective Date

In the August 2021 NOPR, DOE proposed an effective date of 60 days from the publication of the final rule for the proposed definitions. 86 FR 46611, 46620. NEMA and GE Lighting stated that the 60-day effective date proposed for the GSL definitions is insufficient time for manufacturers to respond. NEMA and GE Lighting cited as concerns the potential lack of LED lamp substitutes for lamp types impacted by the amended GSIL and GSL definitions and complying with existing regulations for newly impacted lamp types. (NEMA, No. 9 at pp. 2–3; GE Lighting, No. 14 at p. 2)

NEMA and GE Lighting stated that almost all GSLs are made overseas and described the steps of the manufacturing and retail supply chain. NEMA stated that the supply forecasting process, which includes cancelling and selling affected products, as well as identifying, ordering, and shipping alternative LED products, would require at least 9–12 months for the lamps newly impacted by the GSL definition. NEMA stated that manufacturers would need at least 12 months to adjust supply chains and retailers would need an additional 12 months to sell through inventory. (NEMA, No. 9 at pp. 2–3; GE Lighting, No. 14 at p. 2) NEMA and GE Lighting added that global supply chains are currently under stress due to congested ports, coronavirus disease protocols and outbreaks, electronic chip shortages, and rolling blackouts that lead to unpredictable lighting factory shutdowns in China. NEMA stated that logistics and shipping delays are doubling lead times from 5–6 weeks to 10–12 weeks and electronic chip shortages are increasing component lead times from 1 month to 3 months. (NEMA, No. 9 at p. 4) NEMA added that the date Customs and Border Protection (''CBP'') clears a shipment is the date recorded as the date of manufacture for regulatory purposes. Thus, NEMA stated that with a 60-day effective date, it is possible that a cargo ship could depart with legal cargo that becomes illegal by the time of arrival. (NEMA, No. 9 at pp. 2–3) Further, NEMA stated that to convert the remaining 400 million incandescent decorative lamps (*i.e.,* T-Shape, B, BA, F, G16–1/2, G25, G30, S and M–14 lamps) to LED technology would take approximately 37 months (approximately 3 years) at a current worldwide production and shipping capacity of about 11 million decorative LED lamps per month into the United States. (NEMA, No. 20 at pp. 3–4) NEMA also noted that several LED lamp type options, in particular legacy lamp types, are not available due to technical and financial limitations. NEMA stated that product development and inventory planning take months to years and not all of the DOE proposal is possible or practicable. (NEMA, No. 9 at p. 2)

NEMA stated that medium screw base decorative lamps, 3-way lamps, vibration service lamps, rough service lamps, shatter-resistant lamps, and any other newly regulated lamps would need to be formally tested, certified, and listed in the DOE database under the proposed GSL definitions. NEMA stated that substitute lamps that are not currently regulated products have likely been tested in a manufacturer's laboratory or a less stringent lab for labeling or marketing purposes rather than undergoing the National Voluntary Laboratory Accreditation Program (''NVLAP'') or International Laboratory Accreditation Cooperation (''ILAC'') testing required to meet DOE certification standards. NEMA stated that manufacturers generally have 3 years to prepare newly covered products for legal sale and that testing alone would take several months. (NEMA, No. 9 at pp. 4–5; NEMA, Public Meeting Transcript, No. 7 at pp. 28–30)

Finally, NEMA and GE Lighting stated that a 60-day effective date will result in financial loss to lamp manufacturers due to stranded assets, specifically costs associated with non-cancellable supply contracts, components already purchased based on forecasted production quantities, capital investments already made for labor and production, the value of finished goods that cannot clear customs (import date) within 60 days, and retailer stock resets for all medium screw based decorative lamps, 3-way lamps, vibration service lamps, rough service lamps, and shatter-resistant lamps. NEMA stated that the resulting product shortages and empty store shelves would have a disproportionate impact on smaller manufacturers and smaller retailers. (NEMA, No. 9 at p. 5; GE Lighting, No. 14 at p. 2)

NEMA recommended that DOE align the timing of the definitions with the implementation of new energy conservation standards; however, if DOE moved ahead sooner with the implementation of the definitions, NEMA requested a minimum effective date of 9 to 12 months to account for global supply chain blockages. (NEMA, No. 9 at pp. 5–6) Westinghouse requested clarity on whether products that are newly defined as GSLs will be subject to the existing GSIL standard. (Westinghouse, Public Meeting Transcript, No. 7 at pp. 19–21)

The CEC recommended keeping the 60-day effective date and stated that any stranded lamps should be absorbed by the industry and that allowing the sale of inefficient lamps would merely pass the costs of these products from manufacturers to consumers through higher energy bills and environmental harm. (CEC, No. 15 at pp. 1–2; CEC, No. 15 at p. 4; CA IOUs, No. 17 at p. 2) NYSERDA stated that though the 60-day effective date may seem brief, the expanded GSL definition was initially proposed by DOE over 5 years ago and the market has matured significantly since then. (NYSERDA, No. 12 at p. 2)

The CA IOUs stated that they support the proposed definitions for GSLs and GSILs to become effective 60 days after adoption. The CA IOUs stated that because DOE's existing GSIL standards only prohibit the manufacture or import of non-compliant light bulbs, rather than the sale, retailers may continue to sell non-compliant GSILs already in the U.S. when the definitions become effective. Regarding products en route that may become ineligible for importation, the CA IOUs stated that as the GSL definitions NOPR was published on August 19, 2021, a 60-day effective date is a reasonable gap between adoption and enactment of the expanded GSL definition. The CA IOUs stated that risk-averse planners would have anticipated the GSL backstop and definitions nine months ago with the change of the administration, and thus wholesale market disruption from a short 60-day timeframe should be avoidable. Further, the CA IOUs stated that since January 2020 when California implemented the revised GSL and GSIL definitions and a 45 lm/W minimum energy standard a full range of compliant GSLs have been available in California and there has been no market disruption. The CA IOUs stated that the fact that consumers want to buy incandescent bulbs defines the market

failure that the energy efficiency standards were designed to address. The CA IOUs stated that DOE should take steps to minimize any market disruption caused by the transition; however, regulation is necessary to ensure a thorough and quick transition. (CA IOUs, No. 17 at pp. 2–3; CA IOUs, Public Meeting Transcript, No. 7 at pp. 23–24, 32–33)

NEMA responded that the reason manufacturers are still sourcing and supplying incandescent lamps is because customers are buying them. (NEMA, Public Meeting Transcript, No. 7 at p. 28) GE Lighting stated that the market transformation to LED technology has been happening rapidly noting that since 2016–2017, when DOE began its review of GSLs, a big chunk of the market has by itself converted to LED technology and will continue to do so. (GE Lighting, Public Meeting Transcript, No. 7 at pp. 33–35) The Edison Electric Institute (''EEI'') stated that since LED lamps for GSL shipments have increased from around 10 percent several years ago to now 70 to 75 percent of the market, the industry should not be characterized as a ''market failure.'' (EEI, Public Meeting Transcript, No. 7 at pp. 36–37)

Furthermore, Westinghouse stated that manufacturers cannot choose to stop producing products based off speculations for future regulations, and instead need certainty from DOE through a final rule followed by adequate time to adjust. (Westinghouse, Public Meeting Transcript, No. 7 at pp. 24–25) GE Lighting added that manufacturers must respond to demand and if they discontinue their incandescent product line, another manufacturer would take that market space up. GE Lighting stated that its product line can only be controlled when the regulation goes final. (GE Lighting, Public Meeting Transcript, No. 8 at pp. 25–27)

A lamp covered as a GSL or GSIL under the amended definitions would be subject to any energy conservation standard applicable to that lamp as a GSL or GSIL beginning on the effective date of this final rule, including the 45 lm/W GSL backstop requirement, if applicable. DOE notes that of the lamps newly covered under the amended definitions adopted in this final rule, only certain lamps will be subject to existing standards, *i.e.,* lamp types for which exemption from the GSIL definition is discontinued. *See* 10 CFR 430.32(x)(1). Generally, the energy conservation standards apply to covered products as manufactured. (*See* 42 U.S.C. 6302 and 42 U.S.C. 6303) However, as noted by the CA IOUs, the GSIL energy conservation standards at 10 CFR 430.32(x)(1) apply to GSILs manufactured on or after January 1, 2012, January 1, 2013, and January 1, 2014, depending on the rated lumens of the lamp. As such, in determining whether compliance is required by a lamp newly covered by the amended GSIL definition, the compliance dates in 10 CFR 430.32(x)(1) would be applicable. To determine the appropriateness of a 60-day effective date, DOE examined its impact on these new GSILs subject to GSIL standards.

Specifically, the following lamp types become GSILs under the GSIL definition adopted in this final rule and subject to existing GSIL standards: (1) T shape lamp that uses not more than 40 watts or has a length of more than 10 inches; (2) B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp of 40 watts or less; (3) reflector lamp; (4) rough service lamp; (5) shatter-resistant lamp; (6) 3-way lamp; and (7) vibration service lamp. Per the GSIL definition established in this rule, these lamp types must have a medium screw base; 310–2,600 lumens (232–1,950 lumens for modified spectrum); and operate within 110 and 130 V. DOE's review of the market indicates that there are LED lamp substitutes available for these lamp types. The incandescent version of rough service and vibration service lamps use filaments strengthened with additional supports. The incandescent version of shatter-resistant lamps has a reinforced outer bulb to contain glass pieces in the event the bulb breaks. LED lamps inherently provide the consumer with these features because they do not have metal filaments and LED lamps are available that do not use glass outer bulbs. DOE has also found that there are product offerings of LED lamps that are medium screw base, 310–2,600 lumens, operate within 110 and 130 volts and are a (1) T shape lamp of 749 lumens [11] or less (equivalent of 40 watts or less) or has a length of more than 10 inches (2) B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp of 749 lumens or less [12] (equivalent of 40 watts or less); (3) reflector lamp, or (4) 3-way lamp. Therefore, DOE finds that there will be substitutes for lamps newly regulated as GSILs.

As proposed in the August 2021 NOPR, DOE is establishing a 60-day effective date for this rule in recognition of the need to act promptly in connection with the statutory requirements. As indicated by commenters, a substantial part of the lamp market has already transitioned to LED technology. DOE does not find that the impact on certain types of incandescent/halogen lamps will disrupt the market and thereby substantively impact consumers, manufacturers, or retailers. DOE acknowledges that manufacturers will have to comply with the statutory backstop requirement for GSLs when effective. It is DOE's intent that newly regulated GSILs will not be required to comply with multiple standards in a short period of time. DOE intends to do this by using its enforcement discretion in the period after this rule is effective, but before the final rule implementing the backstop becomes effective. Hence, DOE finds that an effective date of 60 days after the publication of this final rule is appropriate.

2. GSL Backstop Effective Date

In addition to the expanded GSL definition, NYSERDA, the AGs, the CEC, Joint Comment, and the CA IOUs recommended that DOE promptly implement the 45 lm/W minimum requirement for GSLs. The CEC and CA IOUs stated that the 45 lm/W backstop has been triggered and is not a discretionary action; because DOE failed to meet its statutory requirements as of January 1, 2017, DOE has been legally obligated to enforce the backstop for GSLs since January 1, 2020. The CEC stated that the 45 lm/W backstop should be applied immediately for the existing GSL definitions and applied on the operative date of the final rule for the proposed expanded GSL definitions. (CEC, No. 15 at p. 2)

NEMA recommended a two-step approach in enacting a 45 lm/W minimum requirement: (1) Manufacture-by date of certain lamp types in effect one year after final rule publication in the **Federal Register**, and (2) sell-by date of same lamp types effective one year following manufacture-by date. (NEMA, No. 9 at pp. 5–6) NEMA stated it is not opposed to regulating different lamp groups in different years. NEMA and GE Lighting suggested regulating A-line lamps first, followed by reflector lamps, then decorative lamps, all separated by at least a year to account for timing of manufacturer and retailer resets. NEMA recommended that decorative lamp types follow A-lamps by a minimum of two years, as the decorative lamp market is less transitioned to LEDs. GE Lighting agreed, adding that the A-line market has the highest percentage of LED socket penetration followed by

[11] DOE determined that an incandescent lamp of 40 watts or less produces a maximum lumen output of 749 lumens. The threshold of 749 lumens is based on DOE's GSIL energy conservation standards which require lamps with 750—1049 lumens to have a maximum wattage of 43 W (see 10 CFR 430.32(x)(1)).

[12] Ibid.

reflector lamps and then decorative lamps have the least. GE Lighting also added that product capacity is higher for LED A-line lamps and much lower for LED decorative lamps. NEMA added that exempted reflector lamps (R20, R30 and R40) could also be regulated using the current IRL regulations in a separate phased-in year. NEMA recommended an end date for manufacture/import and a year-later date for sell through for any regulation. NEMA stated that this approach would allow sell through to clear out existing incandescent inventory, avoid stranded assets and empty store shelves, and have a limited effect on energy saving due to the short life of the lamps. (NEMA, No. 9 at pp. 9–10; GE Lighting, No. 14 at pp. 2–3)

The CA IOUs stated that DOE should issue the GSL backstop standard without delay and consider phased-in effective dates for certain lamps per the provision in EISA and as deemed necessary based on information received from manufacturers and retailers. (CA IOUs, No. 17 at pp. 2–3) The CA IOUs stated that the 45 lm/W efficacy standard is far below typical LED performance and recommended that after implementing the January 2017 Definitions, DOE undertake further rulemakings for GSILs and GSLs as soon as possible. (CA IOUs, No. 17 at p. 3) NYSERDA stated that its 2020 Stocking and Shelving Survey [13] study found that most retailers rely on manufacturers to provide compliant products and manufacturers anticipate increases in standards but will not initiate product changes without a high level of certainty that the requirements will go into effect. (NYSERDA, No. 10 at pp. 4–5; AGs, No. 11 at p. 2)

ASAP stated that DOE could consider implementing the standards in a phased approach with standards going into effect for high-volume lamps sooner than lamps that sell more slowly and need longer to clear inventory. ASAP stated, however, while it's important that the standard is implemented smoothly and without needless market disruption, the standard is also two years delayed and is needed to protect the climate and result in savings. (ASAP, Public Meeting Transcript, No. 7 at pp. 30–32) NASEO and ASAP stated Executive Order 13990, under which DOE identified light bulb rules for review, directs DOE to complete work on these and other reviews by December 31, 2021. NASEO and ASAP urged DOE to finalize the GSL definitions and adopt the 45 lm/W backstop standard no later than December 31, 2021. (NASEO, No. 8 at p. 2; ASAP, No. 19 at pp. 2–3)

While this final rule does not propose any new or amended standards or address the applicability of the 45 lm/W backstop requirement, on December 13, 2021, DOE issued a notice of proposed rulemaking to codify in the CFR the backstop requirement for GSLs. 86 FR 70755. As discussed previously, a final rule codifying the backstop requirement is being issued simultaneously with this rule. In that rule, DOE is addressing application of the backstop requirement to lamps that become GSLs or GSILs via this final rule and, consequently, the dates of required compliance for GSLs and GSILs, so that manufacturers of newly regulated GSILs will not have to comply with immediately sequential standards.

H. Analysis

DOE estimated the annualized national economic costs and benefits associated with the expansion of the GSL definition and the proposed implementation of the 45 lm/w backstop relative to a no-new standard case. DOE first considered the product price and energy use of commercially-available lamp options in the expanded GSL definition, including those that would be prohibited under implementation of the 45 lm/W backstop and more efficacious GSLs that would continue to be available. DOE then developed a shipments model to project lamp shipments within the expanded GSL definition for the no-new-standards case and for the 45 lm/W backstop case over a thirty-year period between 2022–2051. Shipments were estimated using a consumer-choice model sensitive to first cost, energy savings, lamp lifetime, and the presence of mercury. The shipments analysis also considered the impact of price learning on product price. Based on the shipments projections, DOE calculated the national consumer economic impacts of the expanded definition and 45 lm/W backstop, by comparing the total installed product costs and operating costs in the 45 lm/W backstop case to the no-new-standards case.

DOE also analyzed the reduction in several greenhouse gases and other pollutants that would result from the expanded GSL definition and the proposed 45 lm/W backstop using emissions intensity factors intended to represent the marginal impacts of the change in electricity consumption associated with amended or new standards.[14] As part of the development of this final rule, for the purpose of complying with the requirements of Executive Order 12866, DOE also considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2. DOE notes that it would have reached the same conclusion presented in this document in the absence of the social cost of greenhouse gases (''SC–GHG), including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

For the purpose of complying with the requirements of Executive Order 12866, DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant (*e.g.,* SC–GHGs). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. DOE exercises its own judgment in

[13] Cadmus Group and Appliance Standards Awareness Project, General Service Lamps: Stocking and Shelving Survey, December 2020. *https://www.nyserda.ny.gov/-/media/Files/Publications/Research/Other-Technical-Reports/21-20-General-Service-Lamps--Stocking-and-Shelving-Survey.pdf.*

[14] The methodology is described in ''Utility Sector Impacts of Reduced Electricity Demand'' (Coughlin, 2014; Coughlin 2019).

presenting monetized climate benefits as recommended by applicable Executive orders and guidance, and, as stated previously, DOE would reach the same conclusion presented in this document in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions (*i.e.,* SC–GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG) (IWG, 2021).[15] The SC–GHGs is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, SC–GHGs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHGs therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD), the DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer-reviewed science.

The SC–GHGs estimates are presented in DOE's technical support document (''TSD'') [16] and were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, in 2009, an interagency working group (IWG) that included the DOE and other executive branch agencies and offices was established to ensure that agencies were using the best available science and to promote consistency in the social cost of carbon ($SC–CO_2$) values used across agencies. The IWG published $SC–CO_2$ estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (IAMs) that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity (ECS)—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane ($SC–CH_4$) and nitrous oxide ($SC–N_2O$) using methodologies that are consistent with the methodology underlying the $SC–CO_2$ estimates. The modeling approach that extends the IWG $SC–CO_2$ methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The $SC–CH_4$ and $SC–N_2O$ estimates were developed by Marten et al. (2015) and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the $SC–CO_2$ estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the $SC–CO_2$ estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the $SC–CO_2$ estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017). Shortly thereafter, in March 2017, President Trump issued Executive Order 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure $SC–CO_2$ estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)).

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021, specifically the $SC–CH_4$ estimates, are used here to estimate the climate benefits for this rulemaking. The E.O. instructs the IWG to undertake a fuller update of the SC–GHG estimates by January 2022 that takes into consideration the advice of the National Academies (2017) and other recent scientific literature.

The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways. First, the IWG found that a global perspective is essential for SC–GHG estimates because it fully captures climate impacts that affect the United States and which have been omitted from prior U.S.-specific estimates due to methodological constraints. Examples of omitted effects include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, and tourism, and spillover pathways such as economic and political destabilization and global migration. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this final rule DOE centers

[15] *See* Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[16] *www.regulations.gov/.*

attention on a global measure of SC–GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. Prior to that, in 2008 DOE presented Social Cost of Carbon (SCC) estimates based on values the Intergovernmental Panel on Climate Change (IPCC) identified in literature at that time. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

While the IWG works to assess how best to incorporate the latest, peer reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: An average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3 percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

The SC–CO_2 values used for this final rule were generated using the values presented in the 2021 update from the IWG's February 2021 TSD. The SC–CO_2 estimates from the latest interagency update are presented in DOE's TSD. For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CO_2 values, as recommended by the IWG.[17] DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case.

The SC–CH_4 and SC–N_2O values used for this final rule were generated using the values presented in the 2021 update from the IWG.[18] The SC–CH_4 and SC–N_2O estimates from the latest interagency update are presented in DOE's TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC–N_2O values, as recommended by the IWG. DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case.

The estimated monetary health benefits from the reduced emissions of SO_2 and NO_X emissions was estimated based on the latest benefit per ton estimates for the relevant sector from the EPA's Benefits Mapping and Analysis Program.[19]

DOE converted the time-series of costs and benefits into annualized values based on the present value in 2021, as shown in Table IV.1. DOE calculated the present value using discount rates of 3 and 7 percent for consumer costs, benefits, and health benefits from the reduction of SO_2 and NO_X emissions and case-specific discount rates for the value of the other greenhouse gas (''GHG'') (CO_2, N_2O, and CH_4) reduction benefits. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown in Table IV.1 in the following section, but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

This final rule constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was subject to review by the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'').

In addition, the Administrator of OIRA has determined that the regulatory action is an ''economically significant'' regulatory action under section (3)(f)(1) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(C) of the Order, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the regulatory action, together with, to the extent feasible, a quantification of those costs. This assessment can be found in DOE's technical support document (''TSD'') and the methodology is summarized in III.H.[20]

[17] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

[18] *See* Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[19] *Estimating the Benefit per Ton of Reducing $PM_{2.5}$ Precursors from 21 Sectors. www.epa.gov/system/files/documents/2021-10/source-apportionment-tsd-oct-2021_0.pdf.*

[20] *www.regulations.gov/.*

TABLE IV.1—ANNUALIZED MONETIZED COSTS, BENEFITS, AND NET BENEFITS

	Million 2020$/year		
	Primary estimate	Low-net-benefits estimate	High-net-benefits estimate
3% discount rate			
Consumer Operating Cost Savings	2,302.0	2,171.2	2,437.6
Climate Benefits *	457.5	442.6	468.6
Health Benefits **	847.1	819.9	867.4
Total Benefits †	3,606.7	3,433.6	3,773.5
Consumer Incremental Product Costs ‡	181.7	186.0	175.5
Net Benefits	3,424.9	3,247.7	3,598.0
7% discount rate			
Consumer Operating Cost Savings	2,177.3	2,072.5	2,287.0
Climate Benefits *	457.5	442.6	468.6
Health Benefits **	721.1	700.6	736.2
Total Benefits †	3,355.9	3,215.8	3,491.8
Consumer Incremental Product Costs ‡	205.8	210.2	199.5
Net Benefits	3,150.1	3,005.6	3,292.2

Note: This table presents the costs and benefits associated with GSLs in the expanded definition shipped in 2022 − 2051. These results include benefits to consumers which accrue after 2051 from the products shipped in 2022–2051. This analysis presents costs and benefits assuming compliance beginning in 2022. As DOE has explained, DOE will release enforcement guidance simultaneously with this rulemaking. If significant compliance behavior changes result from enforcement discretion, both benefits and costs could be reduced for the relevant years, although DOE expects the net benefits will not be significantly changed.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the global social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC–GHG with 3-percent discount rate, but the Department does not have a single central SC–GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

‡ Costs include incremental equipment costs as well as installation costs.

DOE has also reviewed this regulation pursuant to E.O. 13563, issued on January 18, 2011. 76 FR 3281 (Jan. 21, 2011). E.O. 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*www.energy.gov/gc/office-general-counsel*).

For manufacturers of GSLs, the SBA has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. *See* 13 CFR part 121. The size standards are listed by NAICS code and industry description and are available at *www.sba.gov/document/report--table-size-standards-naics-codes*. Manufacturing of GSLs is classified under NAICS 335110, ''Electric Lamp Bulb and Part Manufacturing.'' The SBA sets a threshold of 1,250 employees or less for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small businesses that manufacture GSLs impacted by this rulemaking, DOE conducted a survey using information from DOE's Compliance Certification Database and previous rulemakings. DOE used information from these sources to create a list of companies that potentially manufacture or sell GSLs and would be

impacted by this rulemaking. DOE screened out companies that do not offer products covered by this rulemaking and do not meet the definition of a ''small business.'' DOE determined that 8 companies are small businesses that manufacture GSLs impacted by this final rule.

DOE reviewed the definitions of GSL, GSIL, and related terms adopted in this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that this final rule would not have a significant economic impact on a substantial number of small entities. DOE notes that this final rule would merely define what constitutes a GSL and GSIL. Manufacturers of GSLs and GSILs are required to use DOE's test procedures to make representations and certify compliance with standards, if required. The test procedure rulemakings for CFLs, integrated LED lamps, and other GSLs addressed impacts on small businesses due to test procedure requirements. 81 FR 59386 (Aug. 29, 2016); 81 FR 43404 (July 1, 2016); 81 FR 72493 (Oct. 20, 2016). Hence DOE's lamp test procedures—those that are labeled as test procedures for GSLs, as well as those that are not—as a whole, cover all of the lamps that constitute GSLs in this final rule.

For this reason, DOE concludes and certifies that the definitions adopted in this final rule would not have a significant economic impact on a substantial number of small entities, and the preparation of a FRFA is not warranted.

C. Review Under the Paperwork Reduction Act

Manufacturers of GSLs and GSILs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for GSLs and GSILs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including GSLs and GSILs. 76 FR 12422 (Mar. 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has analyzed this proposed action in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE has determined that this rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix A5 because it is an interpretive rulemaking that does not change the environmental effect of the rule and meets the requirements for application of a CX. *See* 10 CFR 1021.410. Therefore, DOE has determined that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an EA or EIS.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this rule and has determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that

estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) Before promulgating a rule, for which a written statement is needed, Section 205 of UMRA generally requires a Federal agency to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective, or least burdensome alternative that achieves the objectives of the rule. Section 205 allows an agency to adopt an alternative that is not the least costly, most cost effective, or least burdensome alternative if the agency provides an explanation in the final rule of why such an alternative was adopted.

The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*.

This final rule does not require expenditures of $100 million or more in any one year by the private sector. The final rule is likely to result in expenditures of $100 million or more, but there is no requirement that mandates that result. DOE considered and evaluated regulatory alternatives before arriving at the definitions finalized today. These include selecting an effective date for the rule that gives manufacturers more time to find the necessary resources to comply. DOE uses a delayed effective date in this rule to minimize cost and burden to manufacturers of lamp types newly covered under the rule. DOE believes that today's final rule represents the least costly, most effective approach to achieving EPCA's goals of increasing the energy efficiency of covered products through the establishment and amendment of energy conservation standards and promoting conservation measures when feasible. The cost-benefit analysis required by UMRA is discussed in section III.H of this document and the TSD accompanying this rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf*. DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action, which amends definitions for GSL and GSIL, is not a significant energy action because the amendments are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this final rule.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under Section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. 15 U.S.C. 788 (''FEAA''). Section 32 essentially provides in relevant part that, where a final rule authorizes or requires use of commercial standards, the final rule must inform the public of the use and background of such standards. In addition, Section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition. This final rule to amend the definitions of GSL and GSIL does not adopt the use of any new commercial standards.

M. Description of Materials Incorporated by Reference

The modifications to the definition of ''general service lamp,'' ''general service incandescent lamp'' and the associated supporting definitions reference the following commercial standards that are already incorporated by reference in 10 CFR 430.2:

(1) ANSI C78.20–2003, Revision of ANSI C78.20–1995 (''ANSI C78.20''), American National Standard for electric lamps—A, G, PS, and Similar Shapes with E26 Medium Screw Bases, approved October 30, 2003.

(2) ANSI C79.1–2002, American National Standard for Electric Lamps—

Nomenclature for Glass Bulbs Intended for Use with Electric Lamps, approved September 16, 2002.

(3) CIE 13.3–1995 (''CIE 13.3''), Technical Report: Method of Measuring and Specifying Colour Rendering Properties of Light Sources, 1995, ISBN 3 900 734 57 7.

DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of Section 32(b) of the FEAA (*i.e.,* that they were developed in a manner that fully provides for public participation, comment, and review). DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to adopting a final rule.

N. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

Signing Authority

This document of the Department of Energy was signed on April 26, 2022, by Kelly J. Speakes-Backman, Principal Deputy 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 April 28, 2022.

Treena V. Garrett,

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

For the reasons set forth in the preamble, DOE amends part 430 of chapter II of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by:
■ a. Adding in alphabetical order the definitions of ''Black light lamp,'' ''Bug lamp,'' and ''Colored lamp,'';
■ b. Revising the definitions of ''Designed and marketed,'' and ''General service incandescent lamp,'';
■ c. Adding in alphabetical order the definitions of ''General service light-emitting diode (LED) lamp'' and ''General service organic light-emitting diode (OLED) lamp'';
■ d. Revising the definition of ''General service lamp''; and
■ e. Adding in alphabetical order the definitions of ''Infrared lamp'', ''Integrated lamp'', ''LED Downlight Retrofit Kit'', ''Left-hand thread lamp'', ''Light fixture'', ''Marine lamp'', ''Marine signal service lamp'', ''Mine service lamp'', ''Non-integrated lamp'', ''Other fluorescent lamp'', ''Pin base lamp'', ''Plant light lamp'', ''Reflector lamp'', ''Showcase lamp'', ''Sign service lamp'', ''Silver bowl lamp'', ''Specialty MR lamp'', and ''Traffic signal lamp''.

The additions and revisions read as follows:

§ 430.2 Definitions.

* * * * *

Black light lamp means a lamp that is designed and marketed as a black light lamp and is an ultraviolet lamp with the highest radiant power peaks in the UV–A band (315 to 400 nm) of the electromagnetic spectrum.

* * * * *

Bug lamp means a lamp that is designed and marketed as a bug lamp, has radiant power peaks above 550 nm on the electromagnetic spectrum, and has a visible yellow coating.

* * * * *

Colored lamp means a colored fluorescent lamp, a colored incandescent lamp, or a lamp designed and marketed as a colored lamp with either of the following characteristics (if multiple modes of operation are possible [such as variable CCT], either of the below characteristics must be maintained throughout all modes of operation):

(1) A CRI less than 40, as determined according to the method set forth in CIE 13.3 (incorporated by reference; see § 430.3); or

(2) A CCT less than 2,500 K or greater than 7,000 K.

* * * * *

Designed and marketed means exclusively designed to fulfill the indicated application and, when distributed in commerce, designated and marketed solely for that application, with the designation prominently displayed on the packaging and all publicly available documents (*e.g.,* product literature, catalogs, and packaging labels). This definition applies to the following covered lighting products: Fluorescent lamp ballasts; fluorescent lamps; general service fluorescent lamps; general service incandescent lamps; general service lamps; incandescent lamps; incandescent reflector lamps; compact fluorescent lamps (including medium base compact fluorescent lamps); LED lamps; and specialty application mercury vapor lamp ballasts.

* * * * *

General service incandescent lamp means a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however, this definition does not apply to the following incandescent lamps—

(1) An appliance lamp;
(2) A black light lamp;
(3) A bug lamp;
(4) A colored lamp;
(5) A G shape lamp with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);
(6) An infrared lamp;
(7) A left-hand thread lamp;
(8) A marine lamp;
(9) A marine signal service lamp;
(10) A mine service lamp;
(11) A plant light lamp;
(12) An R20 short lamp;
(13) A sign service lamp;
(14) A silver bowl lamp;
(15) A showcase lamp; and
(16) A traffic signal lamp.

General service lamp means a lamp that has an ANSI base; is able to operate

at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps (as defined in this section), or is able to operate at any voltage for non-integrated lamps (as defined in this section); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light emitting diode lamps. General service lamps do not include:

(1) Appliance lamps;

(2) Black light lamps;

(3) Bug lamps;

(4) Colored lamps;

(5) G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);

(6) General service fluorescent lamps;

(7) High intensity discharge lamps;

(8) Infrared lamps;

(9) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases;

(10) Lamps that have a wedge base or prefocus base;

(11) Left-hand thread lamps;

(12) Marine lamps;

(13) Marine signal service lamps;

(14) Mine service lamps;

(15) MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), operate at 12 volts, and have a lumen output greater than or equal to 800;

(16) Other fluorescent lamps;

(17) Plant light lamps;

(18) R20 short lamps;

(19) Reflector lamps (as defined in this section) that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3) and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;

(20) S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);

(21) Sign service lamps;

(22) Silver bowl lamps;

(23) Showcase lamps;

(24) Specialty MR lamps;

(25) T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), nominal overall length less than 12 inches, and that are not compact fluorescent lamps (as defined in this section);

(26) Traffic signal lamps.

General service light-emitting diode (LED) lamp means an integrated or non-integrated LED lamp designed for use in general lighting applications (as defined in this section) and that uses light-emitting diodes as the primary source of light.

General service organic light-emitting diode (OLED) lamp means an integrated or non- integrated OLED lamp designed for use in general lighting applications (as defined in this section) and that uses organic light-emitting diodes as the primary source of light.

* * * * *

Infrared lamp means a lamp that is designed and marketed as an infrared lamp; has its highest radiant power peaks in the infrared region of the electromagnetic spectrum (770 nm to 1 mm); has a rated wattage of 125 watts or greater; and which has a primary purpose of providing heat.

* * * * *

Integrated lamp means a lamp that contains all components necessary for the starting and stable operation of the lamp, does not include any replaceable or interchangeable parts, and is connected directly to a branch circuit through an ANSI base and corresponding ANSI standard lamp-holder (socket).

* * * * *

LED Downlight Retrofit Kit means a product designed and marketed to install into an existing downlight, replacing the existing light source and related electrical components, typically employing an ANSI standard lamp base, either integrated or connected to the downlight retrofit by wire leads, and is a retrofit kit. LED downlight retrofit kit does not include integrated lamps or non-integrated lamps.

Left-hand thread lamp means a lamp with direction of threads on the lamp base oriented in the left-hand direction.

* * * * *

Light fixture means a complete lighting unit consisting of light source(s) and ballast(s) or driver(s) (when applicable) together with the parts designed to distribute the light, to position and protect the light source, and to connect the light source(s) to the power supply.

* * * * *

Marine lamp means a lamp that is designed and marketed for use on boats and can operate at or between 12 volts and 13.5 volts.

Marine signal service lamp means a lamp that is designed and marketed for marine signal service applications.

* * * * *

Mine service lamp means a lamp that is designed and marketed for mine service applications.

* * * * *

Non-integrated lamp means a lamp that is not an integrated lamp.

* * * * *

Other fluorescent lamp means low pressure mercury electric-discharge sources in which a fluorescing coating transforms some of the ultraviolet energy generated by the mercury discharge into light and include circline lamps and include double-ended lamps with the following characteristics: Lengths from one to eight feet; designed for cold temperature applications; designed for use in reprographic equipment; designed to produce radiation in the ultraviolet region of the spectrum; impact-resistant; reflectorized or aperture; or a CRI of 87 or greater.

* * * * *

Pin base lamp means a lamp that uses a base type designated as a single pin base or multiple pin base system.

Plant light lamp means a lamp that is designed to promote plant growth by emitting its highest radiant power peaks in the regions of the electromagnetic spectrum that promote photosynthesis: Blue (440 nm to 490 nm) and/or red (620 to 740 nm), and is designed and marketed for plant growing applications.

* * * * *

Reflector lamp means a lamp that has an R, PAR, BPAR, BR, ER, MR, or similar bulb shape as defined in ANSI C78.20–2003 (incorporated by reference; see § 430.3) and ANSI C79.1–2002 (incorporated by reference; see § 430.3) and is used to provide directional light.

* * * * *

Showcase lamp means a lamp that has a T shape as specified in ANSI C78.20–2003 (incorporated by reference; see § 430.3) and ANSI C79.1–2002 (incorporated by reference; see § 430.3), is designed and marketed as a showcase lamp, and has a maximum rated wattage of 75 watts.

* * * * *

Sign service lamp means a vacuum type or gas-filled lamp that has sufficiently low bulb temperature to

permit exposed outdoor use on high-speed flashing circuits, is designed and marketed as a sign service lamp, and has a maximum rated wattage of 15 watts. Silver bowl lamp means a lamp that has an opaque reflective coating applied directly to part of the bulb surface that reflects light toward the lamp base and that is designed and marketed as a silver bowl lamp.

* * * * *

Specialty MR lamp means a lamp that has an MR shape as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), a diameter of less than or equal to 2.25 inches, a lifetime of less than or equal to 300 hours, and that is designed and marketed for a specialty application.

* * * * *

Traffic signal lamp means a lamp that is designed and marketed for traffic signal applications and has a lifetime of 8,000 hours or greater.

* * * * *

[FR Doc. 2022–09480 Filed 5–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

12 CFR Part 14

[Docket No. OCC–2022–0004]

RIN 1557–AF16

Customer Assistance Group Change of Mailing Address

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Final rule; technical amendment.

SUMMARY: The OCC is issuing this final rule; technical amendment to amend the consumer grievance process appendix in the Consumer Protection in Sales of Insurance regulations by removing an outdated mailing address for the OCC's Customer Assistance Group (CAG) and replacing it with the current mailing address.

DATES: The final rule is effective May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Marta Stewart-Bates, Counsel, or Graham Bannon, Attorney, Chief Counsel's Office, (202) 649–5490, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: On August 5, 2021, the OCC published Bulletin 2021–35, ''Community Reinvestment Act, Fair Housing Act, and Equal Credit Opportunity Act: OCC Contact Information for Certain Notices and Posters,'' [1] which announced the new physical mailing address of the OCC's CAG, ''P.O. Box 53570, Houston, TX 77052.'' The previous CAG mailing address was 1301 McKinney Street, Suite 3450, Houston, Texas 77010–3031. The OCC's regulation in appendix A to 12 CFR part 14 sets forth a consumer grievance process that contains the previous mailing address for the OCC's CAG. This final rule amends appendix A to 12 CFR part 14 to remove the outdated CAG mailing address and replace it with the current CAG mailing address.

Administrative Law Matters

A. Administrative Procedure Act

The OCC is issuing this final rule without prior notice and the opportunity for public comment and without the 30-day delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).[2] Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [3]

The OCC believes that there is good cause to issue this final rule without notice and public procedure because the rule makes a technical change to update a physical mailing address for the OCC's CAG and does not alter any substantive standard. Therefore, there is good cause to dispense with the APA prior notice and public comment process because it is unnecessary since the change of CAG's address in 12 CFR part 14 is a non-substantive, technical amendment to the OCC's rule.

The APA also requires a 30-day delayed effective date, except for (1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause.[4] The OCC finds good cause to publish this final rule with an immediate effective date because, as described above, this final rule merely reflects a change of address in existing regulations and does not alter any substantive standard.

B. Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act [5] requires Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The OCC has sought to present this final rule in a simple and straightforward manner.

C. Paperwork Reduction Act Analysis

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3521, the OCC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently-valid Office of Management and Budget (OMB) control number. The OCC has reviewed this final rule and determined that it does not introduce a new collection of information pursuant to the PRA.

D. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) [6] requires an agency to consider whether the rules it proposes will have a significant economic impact on a substantial number of small entities.[7] The RFA applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b). Consistent with section 553(b)(B) of the APA, the OCC has determined for good cause that general notice and opportunity for public comment is unnecessary because the rule makes a technical change to update a physical mailing address for the OCC's CAG and does not alter any substantive standard, and, therefore, the OCC is not issuing a notice of proposed rulemaking. Accordingly, the OCC has concluded that the RFA's requirements relating to initial and final regulatory flexibility analysis do not apply.

E. Unfunded Mandates Reform Act of 1995

As a general matter, the Unfunded Mandates Reform Act of 1995 (UMRA) [8] requires the preparation of a budgetary impact statement before promulgating a

[1] *https://occ.gov/news-issuances/bulletins/2021/bulletin-2021-35.html.*

[2] 5 U.S.C. 553.

[3] 5 U.S.C. 553(b)(B).

[4] 5 U.S.C. 553(d).

[5] Public Law 106–102, section 722, 113 Stat. 1338, 1471 (1999).

[6] 5 U.S.C. 601 *et seq.*

[7] Under regulations issued by the Small Business Administration, as of February 2021, a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $600 million or less and trust companies with total assets of $41.5 million or less. *See* 13 CFR 121.201.

[8] 2 U.S.C. 1531 *et seq.*

rule that includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. However, the UMRA does not apply to final rules for which a general notice of proposed rulemaking was not published.[9] Consistent with section 553(b)(B) of the APA, the OCC has determined for good cause that general notice and opportunity for public comment is unnecessary because the rule makes a technical change to update a physical mailing address for the OCC's CAG and does not alter any substantive standard, and, therefore, the OCC is not issuing a notice of proposed rulemaking. Accordingly, the OCC has not prepared an economic analysis of the rule under the UMRA.

F. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994,[10] in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, the OCC must consider, consistent with the principles of safety and soundness and the public interest: (1) Any administrative burdens that the final rule places on depository institutions, including small depository institutions and customers of depository institutions, and (2) the benefits of the final rule. This final rule does not impose additional reporting, disclosure, or other requirements on an insured depository institution. Therefore, section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 does not apply to this final rule.

G. The Congressional Review Act

Before a rule can take effect, the Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.,* provides that the OCC must submit to Congress and to the Comptroller General the rule along with a report indicating whether it is a ''major rule.'' In general, if a rule is a ''major rule,'' the CRA provides that unless Congress enacts a joint resolution of disapproval, the rule takes effect the later of: (1) 60 Days after Congress receives the required report or publication of the rule in the **Federal Register**, whichever is later; or (2) the date the rule would otherwise take effect.[11] The CRA defines a ''major rule'' as any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, or (3) a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.[12]

OIRA has determined that this final rule is not a major rule. As required by the CRA, the OCC will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

List of Subjects in 12 CFR Part 14

Banks, banking, Consumer protection, Insurance, National banks, Reporting and recordkeeping requirements.

Office of the Comptroller of the Currency

For the reasons set out in the preamble, 12 CFR part 14 is amended as follows:

PART 14—CONSUMER PROTECTION IN SALES OF INSURANCE

■ 1. The authority citation for part 14 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 24(Seventh), 92, 93a, 1462a, 1463, 1464, 1818, 1831x, and 5412(b)(2)(B).

■ 2. Appendix A to part 14 is revised to read as follows:

Appendix A to Part 14—Consumer Grievance Process

Any consumer who believes that any bank, Federal savings association, or any other person selling, soliciting, advertising, or offering insurance products or annuities to the consumer at an office of the bank or Federal savings association, or on behalf of the bank or Federal savings association, has violated the requirements of this part should contact the Customer Assistance Group, Office of the Comptroller of the Currency, (800) 613–6743, P.O. Box 53570, Houston, TX 77052, or *www.helpwithmybank.gov.*

Benjamin W. McDonough,

Senior Deputy Comptroller and Chief Counsel, Office of the Comptroller of the Currency.

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BILLING CODE 4810–33–P

[9] *See* 2 U.S.C. 1532(a).

[10] 12 U.S.C. 4802(a).

[11] 5 U.S.C. 801(a)(3).

[12] 5 U.S.C. 804(2).

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 329

Liquidity Risk Measurement Standards

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

In Title 12 of the Code of Federal Regulations, parts 300 to 346, revised as of January 1, 2022, make the following corrections:

§ 329.22 [Corrected]

■ 1. Amend § 329.22 in paragraphs (a)(2) introductory text, (a)(2)(ii), (a)(4), and (a)(5), by removing the text ''' in its place wherever it appears.'' wherever it appears.

§ 329.40 [Corrected]

■ 2. Amend § 329.40 in paragraph (a) by adding the words ''An FDIC-supervised institution'' to the beginning of the first sentence.

[FR Doc. 2022–09989 Filed 5–6–22; 8:45 am]

BILLING CODE 0099–10–P

FARM CREDIT ADMINISTRATION

12 CFR Parts 611, 615, 620, 621, 628, and 630

RIN 3052–AD36

Implementation of the Current Expected Credit Losses Methodology for Allowances, Related Adjustments to the Tier 1/Tier 2 Capital Rule, and Conforming Amendments

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or Agency) is amending certain regulations to address changes in U.S. generally accepted accounting principles (U.S. GAAP). These amendments modify FCA's capital and other regulations, including certain regulatory disclosure requirements.

DATES: The final rule is effective on January 1, 2023.

FOR FURTHER INFORMATION CONTACT:

Technical information: Ryan Leist, *LeistR@fca.gov,* Associate Director, Operations, Management, and Accounting Team, Corbin West, *WestC@fca.gov,* Policy Analyst (capital markets), or Jeremy R. Edelstein,

EdelsteinJ@fca.gov, Associate Director, Finance and Capital Markets Team, Office of Regulatory Policy, (703) 883–4414, TTY (703) 883–4056; or *ORPMailbox@fca.gov;*

or

Legal information: Jennifer Cohn, *CohnJ@fca.gov,* Assistant General Counsel, Office of General Counsel, (720) 213–0440, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. Objectives of the Final Rule

FCA's objectives in adopting this rule are to:

- Ensure the Farm Credit System's (System) capital requirements, including certain regulatory disclosures, reflect the current expected credit losses methodology (CECL), which revises the accounting for credit losses under U.S. GAAP; and
- Ensure conforming amendments to other regulations accurately reference credit losses.

B. Background

In 1916, Congress created the System to provide permanent, stable, affordable, and reliable sources of credit and related services to American agricultural and aquatic producers.[1] As of January 1, 2022, the System consists of three Farm Credit Banks, one agricultural credit bank, 64 agricultural credit associations, one Federal land credit association, several service corporations, and the Federal Farm Credit Banks Funding Corporation (Funding Corporation). System banks (including both the Farm Credit Banks and the agricultural credit bank) issue Systemwide consolidated debt obligations in the capital markets through the Funding Corporation,[2] which enables the System to extend short-, intermediate-, and long-term credit and related services to eligible borrowers. Eligible borrowers include farmers, ranchers, aquatic producers and harvesters, their cooperatives, rural utilities, exporters of agricultural commodities products, farm-related businesses, and certain rural homeowners. The System's enabling statute is the Farm Credit Act of 1971, as amended (Act).[3]

On September 23, 2019, FCA published in the **Federal Register** a notice of proposed rulemaking (proposed rule or proposal) seeking public comment on revisions to certain regulations to address changes to credit loss accounting under U.S. GAAP.[4] In particular, FCA proposed to amend certain rules to reflect the Financial Accounting Standards Board's (FASB) issuance of Accounting Standards Update (ASU) No. 2016–13, Financial Instruments—Credit Losses, Topic 326, Measurement of Credit Losses on Financial Instruments (ASU 2016–13). FASB's new accounting standard for credit losses applies to all System institutions.[5]

ASU 2016–13 introduces CECL, which replaces the incurred loss methodology for financial assets measured at amortized cost. This update is discussed in more detail in the next section, Overview of Changes to U.S. GAAP. FCA proposed to revise the tier 1/tier 2 capital rule in part 628 to distinguish which credit loss allowances under the new accounting standard would be eligible for inclusion in a System institution's regulatory capital.

FCA's tier 1/tier 2 capital rule in part 628 are similar to the standardized approach capital rules the Federal banking regulatory agencies (FBRAs)[6] adopted for the banking organizations they regulate (U.S. Rule), while taking into account the cooperative structure and the organization of the System. FCA's proposed CECL rule was similar to the FBRAs' final CECL rule, which was published in February 2019.[7]

Unlike the CECL rule adopted by the FBRAs, FCA did not propose a phase-in of the day-one impacts of CECL on regulatory capital ratios. The CECL Transition Provision section below discusses why a transition period for System institutions is unnecessary and would create undue burden and complexity.

As part of efforts to address the disruption of economic activity in the United States caused by the spread of COVID–19, the FBRAs adopted a second CECL transition provision.[8] This second CECL transition provided banking organizations that were required to adopt CECL for purposes of U.S. GAAP on January 1, 2020, the option to delay, for up to two years, an estimate of CECL's impact on regulatory capital, followed by a three-year transition period (*i.e.,* a five-year transition period in total).

As discussed below, FCA received four comment letters on the proposed

[1] The Federal Agricultural Mortgage Corporation (Farmer Mac) was chartered in 1987 as a Farm Credit System institution. Farmer Mac operates secondary market activities for agricultural real estate mortgage loans, rural housing mortgage loans, rural utility cooperative loans, and agriculture and rural development loans guaranteed by the United States Department of Agriculture (USDA). The FCA has a separate set of capital regulations, at subpart B of part 652, that apply to Farmer Mac. This rulemaking does not affect Farmer Mac, and the use of the term ''System institution'' in this preamble and rule does not include Farmer Mac.

[2] The Funding Corporation was established pursuant to section 4.9 of the Farm Credit Act of 1971, as amended, and is owned by all System banks. The Funding Corporation is the fiscal agent and disclosure agent for the System. The Funding Corporation is responsible for issuing and marketing debt securities to finance the System's loans, leases, and operations and for preparing and producing the System's financial results.

[3] 12 U.S.C. 2001–2279cc. The Act is available at *www.fca.gov* under ''Laws and regulations'' and ''Statutes.''

[4] *See* 84 FR 49684. Section 621.3 requires System institutions to prepare financial statements in accordance with U.S. GAAP (referred to as GAAP in FCA regulations), except as otherwise directed by statutory and regulatory requirements. Previously, FCA had issued an informational memorandum providing initial information on the new accounting standard. *See* Informational Memorandum, New Accounting Standard on Financial Instruments—Credit Losses, dated September 1, 2016.

[5] FCA regulation § 628.2 defines System institution, for capital rule purposes, as a System bank, an association, and any other institution chartered by the FCA that the FCA determines should be subject to FCA's capital rules.

[6] The FBRAs are the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation.

[7] *See* FBRA's final CECL rule at 84 FR 4222 (February 14, 2019). FCA staff met with System representatives during the development of FCA's proposed rule to seek their input on certain issues. The questions discussed were similar to the questions asked in the preamble to the FBRAs' proposed CECL rule (83 FR 22312, May 14, 2018). FCA staff considered this input in developing the proposed rule.

[8] *See* 85 FR 17723 (March 31, 2020) (interim final rule); 85 FR 61577 (September 30, 2020) (final rule).

rule. These comments, together with FCA's responses to those comments, are addressed in the Final Rule section below. FCA is finalizing most provisions as proposed. However, FCA is making changes to certain provisions in response to comments, as discussed below.

C. Overview of Changes to U.S. GAAP

In June 2016, FASB issued ASU No. 2016–13, Topic 326, Financial Instruments—Credit Losses,[9] which revises the accounting for credit losses under U.S. GAAP. In pertinent part, ASU No. 2016–13:

- Introduces CECL, which replaces the incurred loss methodology for financial assets measured at amortized cost;
- Introduces the term purchased credit deteriorated (PCD) assets, which replaces the term purchased credit impaired (PCI) assets;
- Modifies the treatment of credit losses on available-for-sale (AFS) debt securities; and
- Requires certain disclosures of credit quality indicators by year of origination (or vintage).

CECL differs from the incurred loss methodology in several key respects. CECL requires System institutions to recognize lifetime expected credit losses for financial assets measured at amortized cost, not just those credit losses that have been incurred as of the reporting date. CECL also requires the incorporation of reasonable and supportable forecasts in developing an estimate of lifetime expected credit losses, while maintaining the current requirement for System institutions to consider past events and current conditions. Furthermore, the probable threshold for recognition of allowances in accordance with the incurred loss methodology is removed under CECL. Estimating expected credit losses over the life of an asset under CECL, including consideration of reasonable and supportable forecasts, results in earlier recognition of credit losses than under the existing incurred loss methodology.

In addition, CECL replaces multiple impairment approaches in existing U.S. GAAP. CECL allowances will cover a broader range of financial assets than allowance for loan losses (ALL) under the incurred loss methodology. Under the incurred loss methodology, in general, ALL covers credit losses on loans held for investment and lease financing receivables, with additional allowances for certain other extensions of credit and allowances for credit losses on certain off-balance sheet credit exposures (with the latter allowances presented as a liability).[10] These exposures will be within the scope of CECL. In addition, CECL covers credit losses on held-to-maturity (HTM) debt securities.

As mentioned above, ASU No. 2016–13 also introduces PCD assets as a replacement for PCI assets. The PCD asset definition covers a broader range of assets than the PCI asset definition. CECL requires System institutions to estimate and record credit loss allowances for a PCD asset at the time of purchase. The credit loss allowance is then added to the purchase price to determine the amortized cost basis of the asset for financial reporting purposes. Post-acquisition increases in credit loss allowances on PCD assets will be established through a charge to earnings. This is different from the current treatment of PCI assets, for which System institutions are not permitted to estimate and recognize credit loss allowances at the time of purchase. Rather, in general, credit loss allowances for PCI assets are estimated after the purchase only if there is deterioration in the expected cash flows from the assets.[11]

ASU No. 2016–13 also introduces new requirements for AFS debt securities. The new accounting standard requires a System institution to recognize credit losses on individual AFS debt securities through credit loss allowances, rather than through direct write-downs, as is currently required under U.S. GAAP. AFS debt securities will continue to be measured at fair value, with changes in fair value not related to credit losses recognized in other comprehensive income. Credit loss allowances on an AFS debt security are limited to the amount by which the security's fair value is less than its amortized cost.

Upon adoption of CECL, a System institution will record a one-time adjustment to its credit loss allowance as of the beginning of its fiscal year of adoption equal to the difference, if any, between the amount of credit loss allowance required under the incurred loss methodology and the amount of credit loss allowance required under CECL. Except for PCD assets, the adjustment to credit loss allowance would be recognized with offsetting entries to deferred tax assets (DTAs), if appropriate, and to the fiscal year's beginning retained earnings.

The effective date of ASU No. 2016–13 varies for different financial institutions. The original effective date for public business entities (PBEs) that are not Securities and Exchange Commission (SEC) filers, such as the Funding Corporation,[12] was the fiscal year beginning after December 15, 2020, including interim periods within that fiscal year, and that was the timeframe in effect when FCA published the proposed CECL rule. After publication, on October 18, 2019, FASB amended the effective dates of certain major accounting standards, including ASU No. 2016–13. Specifically, for entities such as the Funding Corporation, ASU No. 2016–13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years.[13] System institutions will implement the new standard on January 1, 2023, and Systemwide combined financial statements for the quarter ending March 31, 2023, will reflect the new standard.[14]

D. Regulatory Capital

Changes necessitated by CECL to a System institution's retained earnings, DTAs, and allowances will affect the institution's regulatory capital ratios.[15]

[9] ASU 2016–13 covers measurement of credit losses on financial instruments and includes three subtopics within Topic 326: (i) Subtopic 326–10 Financial Instruments—Credit Losses—Overall; (ii) Subtopic 326–20: Financial Instruments—Credit Losses—Measured at Amortized Cost; and (iii) Subtopic 326–30: Financial Instruments—Credit Losses—Available-for-Sale Debt Securities.

[10] ''Other extensions of credit'' includes trade and reinsurance receivables, and receivables that relate to repurchase agreements and securities lending agreements. ''Off-balance sheet credit exposures'' includes off-balance sheet credit exposures not accounted for as insurance, such as loan commitments, standby letters of credit, and financial guarantees. Note that credit losses for off-balance sheet credit exposures that are unconditionally cancellable by the issuer are not recognized under CECL.

[11] The System currently holds limited PCI assets, which have generally been acquired through business combinations. FCA does not believe the amount of PCD assets in the System after the adoption of CECL will be materially different.

[12] A PBE that is not an SEC filer includes: (1) An entity that has issued securities that are traded, listed, or quoted on an over-the-counter market, or (2) an entity that has issued one or more securities that are not subject to contractual restrictions on transfer and is required by law, contract, or regulation to prepare U.S. GAAP financial statements (including footnotes) and make them publicly available periodically. For further information on the definition of a PBE, refer to ASU No. 2013–12, Definition of a Public Business Entity, issued in December 2013. Since, as discussed above, the Funding Corporation is the System's fiscal and disclosure agent, the CECL effective date for the System is based on its effective date for the Funding Corporation. The Funding Corporation satisfies the definition of a PBE that is not an SEC filer.

[13] *See* FASB ASU 2019–10 Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) Effective Dates, issued in November 2019.

[14] If FASB were to amend the effective date again, System implementation may similarly be delayed.

[15] These capital ratios are specified in § 628.10.

Specifically, retained earnings are a key component of a System institution's common equity tier 1 (CET1) capital.[16] An increase in a System institution's allowances, including those estimated under CECL, generally will reduce the institution's earnings or retained earnings, and therefore its CET1 capital.[17]

Depending on the nature of the difference, DTAs arising from temporary differences (temporary difference DTAs) are included in a System's institution's risk-weighted assets or are deducted from CET1 capital.[18] Increases in allowances generally give rise to increases in temporary difference DTAs that will partially offset the reduction in earnings or retained earnings.[19] Under § 628.20(d)(3), the ALL is included in a System institution's tier 2 capital up to 1.25 percent of its standardized total risk-weighted assets (as defined in § 628.2) not including any amount of the ALL.[20]

II. Summary of the Proposal

A. Proposed Revisions to the Capital Rules To Reflect the Change in U.S. GAAP

To address the forthcoming implementation of changes to U.S. GAAP resulting from the FASB's issuance of ASU No. 2016–13 and to improve consistency between FCA's capital rules and U.S. GAAP, FCA proposed to amend the capital rules in part 628 to identify which credit loss allowances under the new accounting standard would be eligible for inclusion in a System institution's regulatory capital. Because FCA's capital rules are generally similar to the U.S. Rule, FCA's proposed CECL rule was generally similar to the FBRAs' final CECL rule.

In particular, FCA proposed to add adjusted allowances for credit losses (AACL) as a newly defined term in its capital rules. Under the proposal, AACL included credit loss allowances related to financial assets, except for allowances for PCD assets and AFS debt securities.[21] AACL was eligible under the proposal for inclusion in a System institution's tier 2 capital subject to the current limit for including ALL in tier 2 capital under the capital rules.[22] The proposed rule provided separate capital treatment for allowances associated with AFS debt securities and PCD assets that would apply to System institutions upon adoption of ASU 2016–13. Unlike the CECL rule adopted by the FBRAs, FCA did not propose a phase-in of the day-one impacts of CECL on regulatory capital ratios.

FCA's proposed rule also revised capital disclosure requirements that apply to System banks following their adoption of CECL[23] and made conforming amendments to other regulations so they refer to credit loss allowance and reflect the implementation of ASU No. 2016–13.

B. Summary of Comments Received on the Proposal

FCA received four comment letters on the proposed rule: One letter from the Funding Corporation on behalf of the System's Accounting Standards and CECL Workgroups (System Workgroups Letter);[24] one letter from CoBank, ACB (CoBank Letter), a System bank;[25] and one letter each from Northwest Farm Credit Services, an Agricultural Credit Association (Northwest Letter)[26] and Capital Farm Credit, ACA (Capital Letter),[27] both System associations. All commenters generally supported many significant aspects of the proposed rule and expressed similar comments. CoBank expressly stated it supported the System Workgroups Letter. The two associations offered comments consistent with certain aspects of the System Workgroups Letter.

All commenters supported FCA's new defined term ''Adjusted Allowances for Credit Losses'' and the modification to the definition of ''carrying value.'' All the commenters also supported the existing limit on the inclusion of the allowance in tier 2 capital of 1.25 percent of risk-weighted assets.

All commenters asked FCA to follow U.S. GAAP for disclosure and reporting requirements, including the conforming amendments FCA proposed, rather than introducing specific disclosures different than those required by U.S. GAAP. In addition, all commenters suggested the rule should contain a general reference to the effective date required by U.S. GAAP rather than specifying an effective date.

All commenters believe FCA should adopt an optional transition period for the day-one impact CECL may have on institutions' regulatory capital to align more closely with the approach taken by the FBRAs. Additionally, all commenters asked FCA to exclude any day-one impact of CECL from the year-over-year change in CET1 capital referred to in § 628.20(f)(5)(ii), to avoid a negative impact on an institution's ability to make capital distributions, including the payment of patronage.

III. Final Rule

As discussed above, FCA's capital rules are similar to the U.S. Rule, while taking into account the cooperative structure and the organization of the System. This final rule is similar in many respects to the FBRAs' CECL rule.

A. Revisions to the Capital Rules To Reflect the Change in U.S. GAAP

1. Introduction of Adjusted Allowances for Credit Losses as a Newly Defined Term

FCA is adopting as final, without change from the proposal, the proposed definition of the new capital term AACL. As proposed, FCA is revising the capital rules to reflect the revised accounting standard for credit losses under U.S. GAAP as it relates to System institutions' calculation of regulatory capital ratios. The new capital term AACL, which replaces the existing term ALL, applies to all System institutions.

FCA is also adopting without change its proposal, consistent with the treatment of ALL under FCA's existing capital rules, to make amounts of AACL eligible for inclusion in an institution's tier 2 capital up to 1.25 percent of the institution's standardized total risk-weighted assets not including any amount of the AACL.

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[16] FCA's capital rules refer to ''unallocated retained earnings (URE)'' rather than ''retained earnings.'' Section 628.2 defines URE as ''accumulated net income that a System institution has not allocated to a member-borrower.'' This preamble uses the term ''retained earnings,'' because that is the term used in CECL and in U.S. GAAP more generally. For purposes of this preamble, ''retained earnings'' has the same meaning as ''URE.''

[17] However, as discussed above, allowances recognized on PCD assets upon adoption of CECL and upon later purchases of PCD assets generally would not reduce the System institution's earnings, retained earnings, or CET1 capital.

[18] DTAs arising from temporary differences in relation to net operating loss carrybacks are risk-weighted at 100 percent under § 628.32(l)(3). DTAs that arise from net operating loss and tax credit carryforwards, net of any related valuation allowances and net of deferred tax liabilities in accordance with § 628.22(e), are deducted from CET1 capital under § 628.22(a)(3). All other DTAs are risk-weighted at 100 percent under § 628.32(l)(5). DTAs are immaterial at most System institutions.

[19] *See* Accounting Standards Codification Topic 740, ''Income Taxes.''

[20] Under § 628.2, any amount of ALL greater than the 1.25 percent limit is deducted from standardized total risk-weighted assets.

[21] This exclusion of credit loss allowances on PCD assets and AFS debt securities is what differentiates AACL from the term allowance for credit losses (ACL), which is used by the FASB in ASU 2016–13 and which applies to both financial assets and AFS debt securities. Consistent with the proposal and as described in the following sections, the AACL definition includes only those allowances that have been charged against earnings or retained earnings.

[22] *See* existing § 628.20(d)(3).

[23] Section 628.63 requires System banks to disclose items such as capital structure, capital adequacy, credit risk, and credit risk mitigation.

[24] System Workgroups Letter dated November 22, 2019.

[25] CoBank Letter dated November 20, 2019.

[26] Northwest Letter dated November 15, 2019.

[27] Capital Letter dated October 18, 2019.

All commenters supported the new defined term AACL and the continuation of the existing limit on the inclusion of the allowance in tier 2 capital.

CECL allowances cover a broader range of financial assets than the ALL under the incurred loss methodology. Under FCA's existing capital rules, ALL includes valuation allowances that have been established through a charge against earnings to cover estimated credit losses on loans or other extensions of credit as determined in accordance with U.S. GAAP. Under CECL, credit loss allowances represent an accounting valuation account, measured as the difference between the financial assets' amortized cost basis and the amount expected to be collected on the financial assets (*i.e.,* lifetime credit losses). Thus, AACL includes allowances for expected credit losses on HTM debt securities and lessors' net investments in leases that have been established to adjust these assets to amounts expected to be collected, as determined in accordance with U.S. GAAP. AACL also includes allowances for expected credit losses on off-balance sheet credit exposures not accounted for as insurance, as determined in accordance with U.S. GAAP. As described below, however, credit loss allowances related to AFS debt securities and PCD assets are not included in the definition of AACL.

As the FBRAs have said they are doing for the banking organizations that they regulate, FCA intends to monitor the impacts of this 1.25 percent limit on regulatory capital and System institution lending practices after the final rule is effective. FCA's ongoing monitoring will include the review of data, including data provided by System institutions. FCA will also monitor the FBRAs' actions in this area. FCA will consider the information it is monitoring in determining whether a further change to the FCA's capital rules' treatment of AACL might be warranted. To the extent FCA determines further revisions to the capital rules are necessary, the Agency would seek comment through a separate proposal.

2. Definition of Carrying Value

FCA is adopting as final, without change from the proposal, a revision to the definition of carrying value. Under the existing definition at § 628.2, carrying value means, with respect to an asset, the value of the asset on the balance sheet as determined in accordance with U.S. GAAP. Under the final rule, and consistent with the FBRAs' final CECL rule, the definition of carrying value is revised to add a provision that, for all assets other than AFS debt securities and PCD assets, the carrying value is not reduced by any associated credit loss allowance. All commenters supported this proposed revision to the definition of carrying value.

i. Available-for-Sale Debt Securities

Current accounting standards require a System institution to make an individual assessment of each of its AFS debt securities and take a direct write-down for credit losses when such a security is other-than-temporarily impaired. The amount of the write-down is charged against earnings, which reduces CET1 capital and results in a reduction in the same amount to the carrying value of the AFS debt security. ASU 2016–13 revises the accounting for credit impairment of AFS debt securities by requiring System institutions to determine whether a decline in fair value below an AFS debt security's amortized cost resulted from a credit loss, and to record any such credit impairment through earnings with a corresponding allowance.

Similar to the current regulatory treatment of credit-related losses for other-than-temporary impairment, under the final rule all credit losses recognized on AFS debt securities will correspondingly affect CET1 capital and reduce the carrying value of the AFS debt security. Since the carrying value of an AFS debt security is its fair value, which would reflect any credit impairment, credit loss allowances for AFS debt securities required under the new accounting standard are not eligible for inclusion in a System institution's tier 2 capital.

ii. Purchased Credit Deteriorated Assets

The final rule maintains the requirement that valuation allowances be fully charged against earnings in order to be eligible for inclusion in tier 2 capital. The final rule, however, excludes PCD allowances from being included in tier 2 capital; rather, a System institution will calculate the carrying value of PCD assets net of allowances.

Under the new accounting standard, PCD assets are acquired individual financial assets (or acquired groups of financial assets with shared risk characteristics) that, as of the date of acquisition and as determined by an acquirer's assessment, have experienced a more-than-insignificant deterioration in credit quality since origination. The new accounting standard will require System institutions to estimate expected credit losses that are embedded in the purchase price of a PCD asset and recognize these amounts as an allowance as of the date of acquisition. As such, the initial allowance amount for a PCD asset recorded on a System institution's balance sheet will not be established through a charge to earnings. Including allowances in tier 2 capital that have not been charged against earnings would diminish the quality of regulatory capital. Post-acquisition increases in allowances for PCD assets will be established through a charge against earnings.

Accordingly, the final regulation provides that valuation allowances charged to retained earnings, in accordance with U.S. GAAP (*i.e.,* the allowances required at CECL adoption), are eligible for inclusion in tier 2 capital. This treatment of PCD assets, in effect, will reduce a System institution's standardized total risk weighted assets, similar to the proposed treatment for credit loss allowances for AFS debt securities.

Consistent with FCA's proposal and with the FBRAs' final CECL rule, this final rule does not allow System institutions to bifurcate PCD allowances to include post-acquisition allowances in the definition of AACL. As discussed in the preamble to the proposed rule, FCA is concerned a bifurcated approach could create undue complexity and burden for System institutions and believes requiring System institutions to calculate the carrying value of PCD assets net of allowances appropriately accounts for post-acquisition allowances in the calculation of regulatory capital.[28] FCA received no comments concerning not allowing a bifurcated approach.

B. CECL Transition Provision

Unlike the FBRAs' final CECL rule, FCA did not propose and is not adopting an optional phase-in of the day-one impacts of CECL on regulatory capital ratios. The FBRAs included an optional transition period for banking organizations to reduce the potential day-one adverse impacts CECL may have on a banking organization's regulatory capital ratios. The FBRAs included this transition period because of concerns that some banking organizations might face difficulties in capital planning because of uncertainty about the economic environment at the time of CECL adoption.[29]

All commenters asked FCA to adopt an optional transition period for the

[28] 84 FR 49684, 49687 (September 23, 2019).

[29] CECL requires consideration of current and future expected economic conditions to estimate allowances. To an extent, these conditions will not be known until closer to a System institution's CECL adoption date.

day-one impact CECL may have on an institution's regulatory capital to more closely align with the approach adopted by the FBRAs.[30] Two commenters stated that FCA should follow its own objective in the capital rules that became effective January 1, 2017, which was to ensure the System's capital requirements were comparable to the Basel III framework and the U.S. Rule.[31] Two commenters asserted that FCA's statement in the preamble to the proposed rule that all institutions will be sufficiently capitalized to absorb the day-one impacts of CECL is not supported by firm estimates.[32] Additionally, all commenters stated that as of their comment submission date, System institutions had not yet fully implemented CECL and were not able to definitively assess possible capital impacts of the implementation.[33]

FCA disagrees with these commenters. As when FCA proposed this rule, FCA continues to believe a transition provision is unnecessary for any System institution. First, even without a transition period, FCA expects all institutions will be sufficiently capitalized to absorb the day-one impact of CECL for the purpose of complying with regulatory capital requirements. Second, FCA's capital requirements are comparable to the Basel III framework and the U.S. Rule even without an optional phase-in period. Finally, adopting an optional phase-in period would create significant operational burden and complexity with no corresponding benefit to the safety and soundness of System institutions.[34]

The first reason a transition period is not necessary is because even without one, FCA expects all institutions will be sufficiently capitalized to absorb the day-one impact of CECL for the purpose of complying with regulatory capital requirements. FCA expects allowances estimated under CECL will likely increase at most System institutions, causing CET1 capital (including retained earnings) to decrease and tier 2 capital to increase. Total capital, which is generally the most constraining capital ratio for associations, would remain largely unchanged. For System banks, where the tier 1 leverage ratio is generally the most constraining capital ratio, FCA expects credit losses under CECL to result in little to no change for bank allowance levels.[35] FCA continues to believe all System institutions will continue to comply with regulatory capital ratios and buffers without a transition period.[36]

Contrary to the commenters' assertions, FCA's expectations for the day-one impact of CECL are supported by firm estimates. For the proposed rule, FCA analyzed allowance amounts from the Uniform Reports of Financial Condition and Performance (Call Report) for all System institutions under various stress scenarios.[37] For the final rule, FCA analyzed allowance amounts from updated Call Report data for all System institutions and completed a review of select System institutions' model development and implementation of CECL.[38] Additionally, since the proposed rule comment period closed, regulatory capital levels remain satisfactory, indicating the System is well positioned to absorb the day-one impact of CECL. In addition, the credit quality of the System's combined loan portfolio remains strong as of December 31, 2021.[39]

Based on these reviews, unless existing and future expected economic conditions significantly deteriorate after publication of this rule and before the January 1, 2023, effective date of this rule, FCA expects all institutions will be sufficiently capitalized to absorb the day-one impact of CECL for the purpose of complying with regulatory capital requirements. More specifically, FCA continues to believe the regulatory capital ratios of all System institutions—CET1; tier 1; total capital; and tier 1 leverage—will remain above the regulatory minimums and buffers after the implementation of CECL, even without a transition period. FCA considered this analysis as part of its determination not to provide an optional transition period for System institutions.

The second reason a transition period is not necessary is that FCA disagrees with the commenters' position that not adopting an optional phase-in period would diverge from FCA's capital rule objective to ensure the System's capital requirements are comparable to the Basel III framework and the U.S. Rule. FCA views comparability as ensuring the overall regulatory outcome of FCA's capital requirements are comparable with the U.S. Rule as appropriate, taking into account the differences between System institutions and banking organizations subject to the U.S. Rule.[40] While many requirements in FCA's capital rules are similar or identical to requirements in the U.S. Rule, comparability does not mean every provision and requirement in the U.S. Rule should be incorporated into FCA's capital rules. FCA's minimum capital requirements ensure the quality and quantity of capital are comparable to that of the U.S. Rule and reflect principles outlined in the Basel III framework, ensuring an overall uniform standard of capital quality that is consistent and transparent.

In adopting the tier 1/tier 2 capital rule in 2016, FCA did not adopt the majority of phase-in and transitional periods that were included in the U.S. Rule.[41] At the time, FCA determined most of these transitional and phase-in periods were not needed to give System institutions sufficient time to come into

[30] In response to a specific question from FCA on the matter, none of the commenters asked FCA to adopt a mandatory transition provision.

[31] System Workgroups Letter and Northwest Letter.

[32] System Workgroups Letter and Capital Letter.

[33] No commenters provided analysis to support their position. In the proposed rule, FCA requested analysis that would support a transition period or alternatives to a transition period that might accommodate institutions in their implementation of the CECL requirements.

[34] For the same reasons, FCA declines to adopt the second, COVID-related transition period the FBRAs adopted in 2020. In addition, FCA notes that transition period applied only to banking organizations that were required to implement CECL on January 1, 2020.

[35] While each System bank has different strategies and asset compositions, in general, the direct note to associations and investments comprise a majority of each banks' assets. Given these assets held at System banks (and their anticipated allowance levels under CECL), FCA anticipates all banks will maintain regulatory capital compliance.

[36] As noted above, FCA issued an informational memorandum in 2016 titled ''New Accounting Standard on Financial Instruments—Credit Losses.'' This informational memorandum specifically encouraged System institutions to plan and prepare for CECL's potential impact on capital and included seven items for System institutions to consider for the measurement, transition, and implementation of CECL. Institutions that have heeded this planning guidance have had ample opportunity to prepare themselves for CECL's day-one impact.

[37] *See* Call Report Schedule RC Balance Sheet.

[38] FCA also reviewed allowance ratios provided by the FBRAs as of June 30, 2021, which compared allowances for banking organizations that had already adopted CECL and allowance ratios for banking organizations that were still under the incurred loss model.

[39] The Funding Corporation reported strong credit quality in the combined System's loan portfolio with loans classified as Acceptable and Other Assets Especially Mentioned at 98.1 percent on December 31, 2021, compared to 97.5 percent on December 31, 2020. *See* 2021 Annual Information Statement of the Farm Credit System, March 1, 2022.

[40] As noted in FCA's preamble to the proposed tier 1/tier 2 capital rule, FCA changed items from the U.S. Rule as appropriate to account for the differences between System institutions and banking organizations regulated by the FBRAs. *See* 79 FR 52814 (September 4, 2014).

[41] As an example, the U.S. Rule provided for phase-in and transitional periods of certain regulatory deductions and adjustments, minority interests, and temporary inclusions of non-qualifying instruments. The FBRAs provided these transitional periods, in part, to provide banking organizations they regulate sufficient time to build capital to meet the new requirements. *See* 79 FR 52814 (September 4, 2014).

compliance with the new rules.[42] FCA's analysis at the time evidenced that all System institutions would exceed the minimum regulatory capital ratios on the effective date of the rule. Since January 1, 2017, the effective date of the rule, as FCA expected, System capital levels have remained satisfactory and all System institutions have exceeded all minimum regulatory capital requirements as well as applicable capital conservation and leverage buffer requirements.

In general, banking organizations regulated by the FBRAs may have a larger day-one impact from adopting CECL and a phase-in may be more appropriate to ensure their regulatory capital compliance. The lending operations of many of these banking organizations—including unsecured lending such as credit cards—have historically caused banking organizations to experience higher credit losses (as a percentage of loans) than System institutions. In contrast to many banking organizations, the System lends primarily to agriculture and other eligible borrowers in rural areas. Approximately 50 percent of the System's combined loan portfolio is in real estate mortgage and rural residential real estate loans. These real estate loans are generally long-term and well-secured, and they are generally expected to have lower credit losses than commercial real estate loans.

The final reason an optional transition period is not needed is that it would lead to unnecessary complexity and operational burden. An optional transition period would require changes to existing Call Report schedules that would require institutions to change existing reporting processes each year of the transition period. For example, new, more complex calculations would be necessary for each year of the transition period (based on the percentage of the transition amount allowed for the year) for reporting items such as retained earnings, average assets, AACL, and other assets. The Call Report would also need to be updated to reflect new temporary line items such as the CECL transition amount.[43]

If System institutions were not sufficiently capitalized to absorb the day-one impact of CECL, FCA believes the complexity and operational burden of an optional transition period might be warranted to provide relief from regulatory capital requirements. However, all System institutions are expected to be sufficiently capitalized to absorb the day-one impact and comply with regulatory capital requirements without an optional transition period.

An optional transition period could also be difficult to implement and maintain for System institutions in districts that make use of common standardized applications for computing and reporting regulatory capital. A transition period utilized by some institutions in such districts but not by others would appear to complicate supporting the common reporting platforms for those institutions. In addition, allowing an optional transition period would create a lack of comparability among System institutions' capital levels.

The commenters asked FCA to state in this final rule that the Agency will work with individual institutions to provide regulatory relief similar to a transition period if the day-one impacts of CECL cause a significant impact to an individual institution's regulatory capital ratios. FCA confirms the Agency will work with individual institutions if the day-one impact of CECL causes them not to comply with the regulatory capital requirements but does not commit to granting relief. As stated in the preamble to the proposed rule, if closer to the adoption of CECL its day-one impact threatens regulatory capital compliance, FCA may consider options to reduce the unanticipated impacts of implementing CECL. The type of action would depend on, among other factors, the significance of CECL's impact on an individual institution, the institution's capital strategy, business planning, and implementation efforts,[44] and how widespread the issue is throughout the System.

For these reasons, FCA declines to adopt a transition period for the day-one impact CECL may have on an institution's regulatory capital.

C. ''Safe Harbor'' Deemed Prior Approval To Make Cash Distributions

All commenters asked FCA to exclude any day-one CECL impacts from § 628.20(f)(5)(ii).

Section 628.20(f) requires System institutions to obtain prior approval from FCA before making any cash distributions of capital included in tier 1 or tier 2 capital. FCA's ''safe harbor'' deemed prior approval provisions, at § 628.20(f)(5), provide that System institutions are deemed to have prior approval from FCA to distribute cash payments as long as certain conditions are met. One of the conditions, in § 628.20(f)(5)(ii), stipulates that, after any such cash payments have been declared and defined by resolution of the board, the dollar amount of CET1 capital at quarter-end equals or exceeds the dollar amount of CET1 capital on the same quarter-end in the previous calendar year.[45]

Commenters believe FCA should exclude the day-one impacts CECL will have on the dollar amount of CET1 capital from compliance with this condition so that CECL implementation would not impact a System institution's ability to make cash capital distributions, including patronage payments, under the ''safe harbor.'' Commenters seek this exclusion so the existing deemed prior approval process would continue without interruption.

FCA disagrees with this request for several reasons. First, FCA believes it is unlikely the day-one impact would result in CET1 capital declining to the same level of CET1 capital on March 31, 2022 (the quarter-end of the prior year). The ''safe harbor'' essentially limits System institutions (without express FCA prior approval) to distributing net income for the current quarter (in which the distribution is declared and defined by resolution of the board) and the prior 3 quarters.

In practice, System institutions rarely make capital distributions—including paying dividends on preferred stock, making cash patronage payments, or redeeming or revolving equities—that equal net income for the current quarter and prior 3 quarters. Rather, in the last three years, System associations have reported, on average, distributing at least 40 percent of their net income in cash patronage.[46] This means the overwhelming majority of associations have had sufficient capacity both to pay cash patronage and to build capital.

FCA continues to expect System boards to give significant thought to capital distribution decisions and how they impact overall capitalization of their institution, especially regarding a cash payment that equals 12-months of net income. In the unlikely event CECL's day-one impact reduces CET1

[42] FCA did provide a phase-in period of 3 years for the 2.5 percent capital conservation buffer. *See* 81 FR 49720, 49721 (July 28, 2016).

[43] *See* Federal Financial Institutions Examination Council Supplemental Instructions: Interim Final Rules and Notice Issued March 2020, Revision 3: 2020 CECL Transition Provision.

[44] As noted above, FCA issued an informational memorandum in 2016 titled ''New Accounting Standard on Financial Instruments—Credit Losses'' which included seven items for System institutions to consider for the measurement, transition, and implementation of CECL. System institutions were specifically encouraged to plan and prepare for CECL's potential impact on capital.

[45] Note that amendments to the capital rule published at 86 FR 54347 (October 1, 2021) and effective on January 1, 2022, made a minor revision to this provision that does not change the comment or FCA's response.

[46] *See* Call Report Schedule RI–D Changes in Net Worth.

capital to a level where an institution could not use the ''safe harbor'' to make a cash patronage distribution in line with prior years, the appropriateness of making such a cash patronage distribution may be questionable.

Second, in the unlikely event CECL implementation would cause a System institution's CET1 capital to be less than the same quarter-end in the previous calendar year, that does not preclude the institution from paying patronage. An institution that wants to pay cash patronage but that cannot satisfy the ''safe harbor'' deemed prior approval requirements under § 628.20(f)(5) may request the prior approval of FCA for such distribution under § 628.20(f)(2) and (3).[47] In addition, a System institution may allocate equities to its member-borrowers as a form of patronage without needing to satisfy any requirements that could be affected by any day-one impacts from CECL.

D. Disclosures and Regulatory Reporting

FCA is adopting as final the proposed requirement for System banks to update their disclosures required under § 628.63 to reflect the adoption of CECL. Section 628.63 imposes public disclosure requirements for System banks related to the capital requirements contained in part 628. The public disclosure requirements are designed to provide important information to market participants on the scope of application, capital structure, risk exposures, risk assessment processes, capital adequacy of the bank, and techniques the bank uses to identify, measure, monitor, and control risks. The final rule replaces requirements to disclose ALL with requirements to disclose AACL. Additionally, the final rule updates references to ''probable loan losses'' and ''loan losses'' with references to allowance for credit losses (ACL)[48] or AACL, as applicable. FCA did not receive any comments related to the proposed bank disclosure amendments in § 628.63.

To reflect changes in U.S. GAAP concerning CECL, FCA anticipates revising the Call Reports in the first quarter of 2023. These revisions would specify the affected line items in the capital schedules and the newly defined term AACL. In addition, FCA intends to update the Call Report instructions for all references to ALL.

E. Conforming Changes to Other FCA Regulations

FCA is not adopting the proposed requirement for System institutions to provide a vintage year credit loss analysis disclosure in §§ 620.5[49] and 630.20.[50] However, the final rule adopts all the other proposed conforming changes.

1. Final Rule Change for Vintage Year Disclosure

Existing FCA regulations at §§ 620.5 and 630.20 require that the discussion and analysis of risk exposures analyze the ALL.[51] The proposal amended these disclosure requirements to update references to the ALL with the newly defined U.S. GAAP term ACL. The proposal also required a new credit loss analysis disclosure by vintage year.[52]

All commenters noted that a vintage year disclosure of the ACL is not required by U.S. GAAP. The commenters requested FCA not introduce specific disclosure requirements in §§ 620.5 and 630.20 that may result in regulatory disclosures being different than those required by U.S. GAAP. The commenters believe removing the vintage year requirement would eliminate the need for FCA to update regulations in the event of any subsequent changes in U.S. GAAP. Because of the overlap of U.S. GAAP disclosures and FCA's requirement to disclose the ''Allowance for credit losses-to-loans,'' [53] the final rule removes the vintage year requirements for the allowance analysis in §§ 620.5(g)(1)(iv)(B) and 630.20(g)(1)(ii)(B), as requested by the commenters. However, consistent with the proposal, the final rule replaces the term ALL with ACL and requires a discussion of the adequacy of the allowance for credit losses given reasonable and supportable forecasts.

2. Conforming Changes Adopted as Proposed

The proposal made a conforming amendment to replace the key financial ratio ''Allowance for loan losses-to-loans'' with ''Allowance for credit losses-to-loans'' in the selected financial disclosure requirement for banks and associations in § 620.5(f). The commenters requested that FCA retain the existing ratio. The commenters believe retaining the existing ratio would avoid the need to reconcile financial data included in the regulatory financial disclosures with the U.S. GAAP balance sheet. The commenters stated a reconciliation would become necessary if the allowance for off-balance sheet credit exposures, which is a liability for U.S. GAAP purposes, were included within the definitions of ''Allowance for credit losses'' in the proposed rule. The commenters proposed as an alternative to require the denominator of the ratio (loans) be expanded to include total off-balance sheet credit exposures to keep the ratios comparable.

FCA disagrees with the commenters' suggestion and continues to believe System disclosures should remain generally consistent with those of the financial services industry, as they have been since at least 1986. FCA's disclosure requirements in the annual report to shareholders and investors are similar to, though not as extensive as, those required by the SEC and other financial regulators.[54] The disclosure reporting requirements originally adopted by FCA in 1986 were generally similar to the SEC Industry Guide 3, *Statistical Disclosure by Bank Holding Companies (Industry Guide 3).*[55] Subsequent to FCA's proposed CECL rule, the SEC updated and codified certain Industry Guide 3 disclosure requirements, including requirements for a similar Allowance for Credit Losses-to-loans ratio disclosure.[56] The FCA continues to believe that System institution shareholders should have access to comparable disclosures made to shareholders of other financial institutions in order to enhance the borrower ownership and control mandated by the Act.

Similarly, the proposal made a conforming amendment to replace the balance sheet line item ''Allowance for

[47] Section 628.20(f)(2) and (3) provide that at least 30 days prior to the intended action, a System institution must submit a request for approval to FCA for a 30-day review period before it takes the intended action. The request is deemed to be granted if FCA does not notify the System institution to the contrary before the end of the 30-day review period. While the prior approval provisions under § 628.20(f)(2) and (3) do not require any supporting documentation, institutions that have material declines in CET1 capital due to the day-one impact of CECL may want to provide the following supporting documentation in any prior approval request related to CECL's implementation: (1) The institution's historical trends and current projections for capital growth through earnings retention, (2) average cash patronage payments over the last 3 years, (3) projected cash patronage payments over the institution's current planning horizon, and (4) the most recent allowance analysis/study under CECL.

[48] ASU No. 2016–13 removes impairment approaches and related terminology, including replacing the term ALL with ACL.

[49] Governing the contents of the annual report to shareholders.

[50] Governing the contents of the annual report to investors.

[51] *See* §§ 620.5(g)(1)(iv)(B) and 630.20(g)(1)(ii)(B).

[52] *See* proposed §§ 620.5(g)(1)(iv)(B) and 630.20(g)(1)(ii)(B).

[53] *See* §§ 620.5(f)(1)(iii)(F) and 630.20(f)(3)(v).

[54] *See* 50 FR 34711, 34712 (August 27, 1985).

[55] *See* 51 FR 8656 (March 13, 1986).

[56] *See* 85 FR 66108 (October 16, 2020). *See also* 17 CFR 229.1405 (Item 1405) Allowance for Credit Losses.

losses'' with ''Allowance for credit losses'' in the selected financial disclosure requirement for banks and associations in § 620.5(f). Commenters s uggested FCA retain the current § 620.5(f)(1)(i)(D) requirement to disclose the allowance for loan losses, rather than adopting the proposed requirement to disclose the allowance for credit losses. Commenters stated the new requirement could result in regulatory disclosure requirements that are different than those required by U.S. GAAP.

FCA disagrees with the commenters' suggestions regarding the usage of ''Allowance for credit losses'' in § 620.5(f)(1)(i)(D) as FCA believes it is important for users of the annual report to understand the amount of potential credit losses to which each bank and association may be exposed. While certain regulatory disclosures, such as the proposed § 620.5(f)(1)(i)(D), may require a reconciliation with U.S. GAAP, FCA continues to believe shareholders should have access to comparable disclosures provided to shareholders of other financial institutions. By retaining the conforming proposed financial disclosures in the final rule, System institutions will be required to provide transparent and comparable disclosures similar to others in the financial services industry.[57]

FCA received no comments relating to any other proposed conforming change and adopts them as proposed.

A number of existing FCA regulations outside of part 628 refer to ALL or to ''loan loss.'' As discussed above, ASU No. 2016–13 removes impairment approaches and related terminology, including replacing the term ALL with ACL. Accordingly, most of the conforming changes outside of part 628 are to replace ALL or ''loan loss'' with ACL or ''credit loss,'' as appropriate. In addition, several existing regulations that refer to ''allowance for losses'' more appropriately refer to ACL.

Most of the conforming changes to regulations within part 628 (as well as to regulations that refer to regulations within part 628), replace ''ALL'' with ''AACL.'' In the capital disclosures at § 628.63, the final rule replaces references to ''probable loan losses'' and ''loan losses'' with ACL or AACL, as applicable.

The final rule makes conforming changes in the following parts:

- Part 611—Organization
- Part 615—Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations
- Part 620—Disclosure to Shareholders
- Part 621—Accounting and Reporting Requirements
- Part 628—Capital Adequacy of System Institutions
- Part 630—Disclosure to Investors in Systemwide and Consolidated Bank Debt Obligations of the Farm Credit System.

F. Effective Date

Under U.S. GAAP, System institutions are required to implement the new standard for purposes of Systemwide combined financial statements for the Call Report quarter ending March 31, 2023. Thus, the final rule will be effective January 1, 2023, for System institutions.

All commenters recommended that FCA not adopt a specific effective date and instead include a more generic reference to the effective date required by U.S. GAAP. When FCA's proposed rule was published in September of 2019, as discussed above, CECL was scheduled to be effective for PBEs that are not SEC filers, such as the Funding Corporation, on January 1, 2021. After FCA's proposed rule was published, FASB deferred the mandatory effective date of CECL for such entities to January 1, 2023.[58] FCA agrees with System commenters that this final rule should be effective consistent with U.S. GAAP. If FASB changes the effective date of CECL for System institutions, FCA will update the effective date of this final rule consistent with the System's implementation date of CECL.

G. Supervisory Guidance on the ACL

FCA expects to issue supervisory guidance on the ACL and update existing guidance referencing ALL. Until that time, many concepts, processes, and practices detailed in existing supervisory guidance on the ALL continue to remain relevant under CECL. Relevant guidance includes, but is not limited to, information related to management's responsibility for the allowance estimation process, the board of directors' responsibility for overseeing management's process, and the need for institutions to appropriately support and document their allowance estimates.[59] Until new guidance is issued, institutions should consider the relevant sections of existing ALL guidance in their implementation of the new accounting standard.

IV. Regulatory Analysis

A. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), FCA hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities. Each of the banks in the System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, System institutions are not ''small entities'' as defined in the Regulatory Flexibility Act.

B. Congressional Review Act

Under the provisions of the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Management and Budget's Office of Information and Regulatory Affairs has determined that this final rule is not a ''major rule'' as the term is defined at 5 U.S.C. 804(2).

List of Subjects

12 CFR Part 611

Agriculture, Banks, banking, Rural areas.

12 CFR Part 615

Accounting, Agriculture, Banks, banking, Government securities, Investments, Rural areas.

12 CFR Part 620

Accounting, Agriculture, Banks, banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 621

Accounting, Agriculture, Banks, banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 628

Accounting, Agriculture, Banks, banking, Capital, Government securities, Investments, Rural areas.

12 CFR Part 630

Accounting, Agriculture, Banks, banking, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Rural areas.

[57] Commenters did not request changes to similar disclosure requirements in part 630. Since the requirements are similar, FCA considered the comments in connection with those requirements as well and, for the same reasons, declines to amend them.

[58] In November 2019, FASB issued ASU 2019–10 Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) Effective Dates, which amended the effective date of CECL.

[59] Existing supervisory guidance includes: FCA Bookletter 49, Adequacy of Farm Credit System Institutions' Allowance for Loan Losses and Risk Funds, April 26, 2004; FCA Informational Memorandum, Allowance for Loan Losses, June 30, 2009; FCA Exam Manual, Allowance for Loan Losses, November 17, 2015; and FCA Exam Manual, Corporate Governance, September 24, 2021.

For the reasons stated in the preamble, the Farm Credit Administration amends parts 611, 615, 620, 621, 628, and 630 of chapter VI, title 12 of the Code of Federal Regulations as follows:

PART 611—ORGANIZATION

■ 1. The authority citation for part 611 is revised to read as follows:

Authority: Secs. 1.2, 1.3, 1.4, 1.5, 1.12, 1.13, 2.0, 2.1, 2.2, 2.10, 2.11, 2.12, 3.0, 3.1, 3.2, 3.3, 3.7, 3.8, 3.9, 4.3A, 4.12, 4.12A, 4.15, 4.20, 4.25, 4.26, 4.27, 4.28A, 5.9, 5.17, 5.25, 7.0–7.3, 7.6–7.13, 8.5(e) of the Farm Credit Act (12 U.S.C. 2002, 2011, 2012, 2013, 2020, 2021, 2071, 2072, 2073, 2091, 2092, 2093, 2121, 2122, 2123, 2124, 2128, 2129, 2130, 2154a, 2183, 2184, 2203, 2208, 2211, 2212, 2213, 2214, 2243, 2252, 2261, 2279a–2279a–3, 2279b–2279f–1, 2279aa–5(e)); secs. 411 and 412, Pub. L. 100–233, 101 Stat. 1568, 1638, as amended by secs. 403 and 404, Pub. L. 100–399, 101 Stat. 989, 999 (12 U.S.C. 2071 note and 2202 note).

§ 611.515 [Amended]

■ 2. Amend § 611.515(b)(6)(ii)(E) by removing the word ''loan'' and adding in its place the word ''credit''.

§ 611.1122 [Amended]

■ 3. Amend § 611.1122 by:

■ a. Removing in paragraph (e)(6)(iii) the word ''loan'' and adding in its place the word ''credit''; and

■ b. Removing in paragraph (e)(10) the words ''loan losses'' and adding in their place the words ''credit losses'' wherever they appear.

§ 611.1130 [Amended]

■ 4. Amend § 611.1130(b)(4)(i) by removing the words ''allowance for losses'' and adding in their place the words ''allowance for credit losses''.

§ 611.1223 [Amended]

■ 5. Amend § 611.1223(c)(23)(ii) by removing the words ''allowance for losses'' and adding in their place the words ''allowance for credit losses''.

§ 611.1250 [Amended]

■ 6. Amend § 611.1250(b)(5)(i)(B) by removing the words ''loan losses'' and adding in their place the words ''credit losses''.

§ 611.1255 [Amended]

■ 7. Amend § 611.1255(b)(5)(i)(B) by removing the words ''general allowance for losses'' and adding in their place the words ''general allowance for credit losses''.

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

■ 8. The authority citation for part 615 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 8.0, 8.3, 8.4, 8.6, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–8, 2279aa–10, 2279aa–12); sec. 301(a), Pub. L. 100–233, 101 Stat. 1568, 1608, as amended by sec. 301(a), Pub. L. 103–399, 102 Stat 989, 993 (12 U.S.C. 2154 note); sec. 939A, Pub. L. 111–203, 124 Stat. 1326, 1887 (15 U.S.C. 78o–7 note).

§ 615.5050 [Amended]

■ 9. Amend § 615.5050 by:

■ a. Removing in paragraph (c)(1) the words ''allowance for loan losses'' and adding in their place the words ''allowance for credit losses''; and

■ b. Removing in paragraphs (c)(2) through (4) the words ''allowance for losses'' and adding in their place the words ''allowance for credit losses''.

§ 615.5132 [Amended]

■ 10. Amend § 615.5132(a) by removing the words ''loan loss adjustments'' and adding in their place the words ''credit loss adjustments''.

§ 615.5140 [Amended]

■ 11. Amend § 615.5140(b)(4)(ii) by removing the words ''loan loss'' and adding in their place the words ''credit loss''.

§ 615.5200 [Amended]

■ 12. Amend § 615.5200(c)(4) by adding the word ''credit'' before ''losses''.

§ 615.5201 [Amended]

■ 13. Amend § 615.5201 by removing the words ''allowance for loan losses'' and adding in their place the words ''adjusted allowance for credit losses'' in the definition of ''Risk-adjusted asset base''.

§ 615.5351 [Amended]

■ 14. Amend § 615.5351(d) by adding the word ''credit'' before ''loss''.

PART 620—DISCLOSURE TO SHAREHOLDEERS

■ 15. The authority citation for part 620 is revised to read as follows:

Authority: Secs. 4.3, 4.3A, 4.19, 5.9, 5.17, 5.19 of the Farm Credit Act (12 U.S.C. 2154, 2154a, 2207, 2243, 2252, 2254); sec. 424, Pub. L. 100–233, 101 Stat. 1568, 1656 (12 U.S.C. 2252 note); sec. 514, Pub. L. 102–552, 106 Stat. 4102, 4134.

■ 16. Amend § 620.5 by:

■ a. Removing in paragraph (f)(1)(i)(D) the word ''losses'' and adding in its place the words ''credit losses'';

■ b. Removing in paragraph (f)(1)(ii)(B) the words ''loan losses'' and adding in their place the words ''credit losses'';

■ c. Removing in paragraph (f)(1)(iii)(F) the words ''loan losses-to-loans'' and adding in their place the words ''credit losses-to-loans'';

■ d. Revising paragraph (g)(1)(iv)(B); and

■ e. Removing in paragraph (g)(1)(iv)(E) the word ''losses'' and adding in its place the word ''credit losses''.

The revision reads as follows:

§ 620.5 Contents of the annual report to shareholders.

* * * * *

(g) * * *

(1) * * *

(iv) * * *

(B) An analysis of the allowance for credit losses that includes the ratios of the allowance for credit losses to loans and net chargeoffs to average loans, and a discussion of the adequacy of the allowance for credit losses given reasonable and supportable forecasts;

* * * * *

PART 621—ACCOUNTING AND REPORTING REQUIREMENTS

■ 17. The authority citation for part 621 is revised to read as follows:

Authority: Secs. 5.17, 5.19, 5.22A, 8.11 of the Farm Credit Act (12 U.S.C. 2183, 2202, 2202a, 2202d, 2252, 2257a, 2279aa–11); Pub. L. 102–552, 106 Stat. 4102, 4134.

§ 621.5 [Amended]

■ 18. Amend § 621.5 by removing the word ''loan'' and adding in its place the word ''credit'' in the section heading and paragraphs (a) and (b).

§ 621.8 [Amended]

■ 19. Amend § 621.8(c)(2) by removing the word ''loan'' and adding in its place the word ''credit''.

PART 628—CAPITAL ADEQUACY OF SYSTEM INSTITUTIONS

■ 20. The authority citation for part 628 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 8.0, 8.3, 8.4, 8.6, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–8, 2279aa–10, 2279aa–12); sec.

301(a), Pub. L. 100–233, 101 Stat. 1568, 1608, as amended by sec. 301(a), Pub. L. 103–399, 102 Stat 989, 993 (12 U.S.C. 1254 note); sec. 939A, Pub. L. 111–203, 124 Stat. 1326, 1887 (15 U.S.C. 78o–7 note).

■ 21. Amend § 628.2 by:
■ a. Adding in alphabetical order a definition for ''Adjusted allowances for credit loss (AACL)'';
■ b. Removing the definition of ''Allowances for loan losses (ALL)''; and
■ c. Adding a sentence at the end of the definition of ''Carrying value'';
■ d. Revising paragraph (2) of the definition of ''Standardized total risk-weighted assets''.

The additions and revision reads as follows:

§ 628.2 Definitions.

* * * * *

Adjusted allowances for credit losses (AACL) means valuation allowances that have been established through a charge against earnings or retained earnings for expected credit losses on financial assets measured at amortized cost and a lessor's net investment in leases that have been established to reduce the amortized cost basis of the assets to amounts expected to be collected as determined in accordance with GAAP. For purposes of this part, adjusted allowances for credit losses includes allowances for expected credit losses on off-balance sheet credit exposures not accounted for as insurance as determined in accordance with GAAP. Adjusted allowances for credit losses excludes allowances created that reflect credit losses on purchased credit deteriorated assets and available-for-sale debt securities.

* * * * *

Carrying value * * * For all assets other than available-for-sale debt securities or purchased credit deteriorated assets, the carrying value is not reduced by any associated credit loss allowance that is determined in accordance with GAAP.

* * * * *

Standardized total risk-weighted assets * * *

(2) Any amount of the System institution's adjusted allowance for credit losses that is not included in tier 2 capital.

* * * * *

§ 628.20 [Amended]

■ 22. Amend § 628.20(d)(3) by removing the word ''ALL'' and adding in its place the word ''AACL'' wherever it appears.

§ 628.22 [Amended]

■ 23. Amend § 628.22(c) by removing the word ''ALL'' in footnote 6 and adding in its place the word ''AACL''.

■ 24. Amend § 628.63(c) in Table 5 by revising entries (a)(5), (e)(5), and (g) and footnote 6 to read as follows:

§ 628.63 Disclosures.

* * * * *

(c) * * *

TABLE 5 TO § 628.63 [1]—CREDIT RISK: GENERAL DISCLOSURES

Qualitative Disclosures	(a) * * * (5) Description of the methodology that the System bank uses to estimate its adjusted allowance for credit losses, including statistical methods used where applicable;
* *	* * * * * * *
	(e) * * * (5) The balance in the adjusted allowance for credit losses at the end of each period according to GAAP; and
* *	* * * * * * *
	(g) Reconciliation of changes in adjusted allowance for credit losses.[6]
* *	* * * * * * *

[1] This Table 5 does not cover equity exposures, which should be reported in Table 9 of this section.

* * * * * * * *

[6] The reconciliation should include the following: A description of the allowance; the opening balance of the allowance; charge-offs taken against the allowance during the period; amounts provided (or reversed) for estimated credit losses during the period; any other adjustments (for example, exchange rate differences, business combinations, acquisitions and disposals of subsidiaries), including transfers between allowances; and the closing balance of the allowance. Charge-offs and recoveries that have been recorded directly to the income statement should be disclosed separately.

* * * * *

PART 630—DISCLOSURE TO INVESTORS IN SYSTEMWIDE AND CONSOLIDATED BANK DEBT OBLIGATIONS OF THE FARM CREDIT SYSTEM

■ 25. The authority citation for part 630 is revised to read as follows:

Authority: Secs. 4.2, 4.9, 5.9, 5.17, 5.19 of the Farm Credit Act (12 U.S.C. 2153, 2160, 2243, 2252, 2254); sec. 424, Pub. L. 100–233, 101 Stat. 1568, 1656 (12 U.S.C. 2252 note); sec. 514, Pub. L. 102–552, 106 Stat. 4102, 4134.

■ 26. Amend § 630.20 by:
■ a. Removing in paragraph (f)(1)(ii) the word ''losses'' and adding in its place the words ''credit losses'';
■ b. Removing in paragraphs (f)(2)(iii) and (f)(3)(v) the words ''loan losses'' and adding in their place the words ''credit losses''; and
■ c. Revising paragraph (g)(1)(ii)(B).

The revision reads as follows:

§ 630.20 Contents of the annual report to investors.

* * * * *

(g) * * *
(1) * * *
(ii) * * *

(B) An analysis of the allowance for credit losses to loans and net chargeoffs to average loans and a discussion of the adequacy of the allowance for credit losses given reasonable and supportable forecasts.

* * * * *

■ 27. Revise appendix A to part 630 to read as follows:

Appendix A to Part 630—Supplemental Information Disclosure Guidelines

Supplemental information required by §§ 630.20(m) and 630.40(e) shall contain, at a minimum, the current year financial data for the components listed in the following tables and be presented in the columnar format illustrated in the following tables:

TABLE A—SUPPLEMENTAL BALANCE SHEET INFORMATION

	Banks [1]	Associations [2]	Financial assistance corporation	Eliminations	Combined without insurance fund [3]	Insurance fund and related combination entries	Combined with insurance fund
Cash and investments. Net loans. Restricted assets. Other Assets.							
Total assets.							
Total liabilities. Protected borrower capital [4]. Restricted capital. Capital stock and surplus.							
Total liabilities, protected borrower capital, and capital stock and surplus.							

[1] Provided combined financial data of all FCS banks, including any consolidated subsidiaries of the banks.
[2] Provide association-only combined financial data of all FCS associations.
[3] Provide the combined financial data of all columns on the left.
[4] Any item that is no longer applicable, *e.g., protected borrower stock, may be omitted.*

TABLE B—SUPPLEMENTAL INCOME STATEMENT INFORMATION

	Banks [1]	Associations [2]	Financial assistance corporation	Eliminations	Combined without insurance fund [3]	Insurance fund and related combination entries	Combined with insurance fund
Net interest income. Provision for credit losses. Other income. Other expenses.							
Net Income.							

[1] Provide combined financial data of all FCS banks, including any consolidated subsidiaries of the banks.
[2] Provide association-only combined financial data of all FCS associations.
[3] Provide the combined financial data of all columns on the left.

Dated: April 20, 2022.

Ashley Waldron,

Secretary, Farm Credit Administration Board.

[FR Doc. 2022–08832 Filed 5–6–22; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0511; Project Identifier AD–2022–00397–T; Amendment 39–22043; AD 2022–10–05]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–05–12, which applied to all Gulfstream Aerospace Corporation Model GVII–G500 and GVII–G600 airplanes. AD 2020–05–12 required revising the existing airplane flight manual (AFM) to incorporate revised limitations and procedures. This AD was prompted by reports of two landing incidents in which the alpha limiter engaged in the landing flare in unstable air, resulting in high rate of descent landings and damage to the airplanes. This AD retains certain requirements, and also adds and replaces certain AFM sections with more restrictive limitations and procedures. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 9, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of March 13, 2020 (85 FR 14562, March 13, 2020).

The FAA must receive comments on this AD by June 23, 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 final rule, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/customer-support.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0511.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0511; 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, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Sanford Proveaux, Aerospace Engineer, Certificate Management and Safety Oversight Section, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5566; email: *Sanford.Proveaux@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2020–05–12, Amendment 39–19860 (85 FR 14562, March 13, 2020) (AD 2020–05–12), for all Gulfstream Aerospace Corporation Model GVII–G500 and GVII–G600 airplanes. AD 2020–05–12 required revising the existing AFM to limit the maximum crosswind component for landing and increase the normal approach speeds, based on steady-state winds and wind gusts. AD 2020–05–12 was prompted by a report of a landing incident, which occurred on February 6, 2020, where the alpha (angle of attack) limiter engaged during the landing flare in unstable air, resulting in a high rate of descent landing and damage to the airplane. The FAA issued AD 2020–05–12 to address inappropriate alpha limiter engagement during the landing flare, which can limit pilot pitch authority during a critical phase of flight near the ground, and result in a high rate of descent landing with possible consequent loss of control of the airplane on landing.

Actions Since AD 2020–05–12 Was Issued

After the FAA issued AD 2020–05–12, a second landing event occurred on April 4, 2022. As in the first event, the alpha limiter engaged during the landing flare in unstable air, resulting in a high rate of descent landing and damage to the airplane. In both events, the angle of attack (AOA) protection function (alpha limiter) of the flight control computer (FCC) engaged and overrode the pilot pitch control inputs which the flight control law erroneously predicted would exceed the stall AOA. This resulted in a high rate of descent landing on the runway. Additionally, the pilots in both events had full aft-stick input when the aircraft contacted the runway, and the full-up pitch control did not arrest the high rate of descent landing.

The Model GVII–G500 and GVII–G600 alpha limiter function of the FCC is designed to prevent aerodynamic stalls and operates when airborne and operating in normal control law. The FCC uses many inputs including current AOA, rate of change of AOA, and pilot control stick inputs to determine alpha limiter activation. If the FCC predicts that critical AOA values will be exceeded, the FCC will activate the alpha limiting function. The FCC may activate the alpha limiting function when the AOA is not close to stall. Depending on the rate of AOA increase and pilot stick input, the alpha limiter may command nose down elevator to prevent a stall. It is clear from an analysis of both events that unintended alpha limiter engagement is primarily caused by rapid, large, and oscillating pilot control inputs near approach reference speeds, induced by unstable atmospheric conditions and gusty winds.

The aircraft level hazard is that inappropriate alpha limiter engagement during the landing flare, which can limit the pilot's ability to control pitch during a critical phase of flight near the ground, can result in a high rate of descent landing with possible consequent loss of control of the airplane on landing. It has been determined that the operating limitations mandated by AD 2020–05–12 are not adequate to prevent another occurrence. For these reasons, the AFM wind and gust operating limitations have been further restricted in this AD.

Pilot Adherence to AFM Revisions To Mitigate the Unsafe Condition of Unintended Alpha Limiter Engagement

These more restrictive operating limitations do not relieve a pilot from their other regulatory obligations, including verifying destination wind forecasts prior to departure, monitoring winds en route, verifying that the approach briefing includes a cockpit brief of winds and weather, and confirming that the winds are still within acceptable limits just prior to landing. Pilots are responsible for becoming familiar with this information when performing preflight actions under 14 CFR part 91.103, 91.151, and 91.167. Furthermore, these limitations can only be exceeded when the pilot is exercising their authority under 14 CFR part 91.3.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

This AD retains certain requirements of AD 2020–05–12, which requires the following sections of Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020, which the Director of the Federal Register approved for incorporation by reference as of March 13, 2020 (85 FR 14562, March 13, 2020).

- Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS.''
- Step 8., ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES.''
- Step 11., ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES.''
- Step 15., ''Approach Speed,'' of Section 01–03–40, ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS.''

This AD also requires the following sections of Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020, which the Director of the Federal Register approved for incorporation by reference as of March 13, 2020 (85 FR 14562, March 13, 2020).

- Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS.''
- Steps 3. and 4. of Section 01–34–40, ''Takeoff and Landing Data (TOLD),'' of Chapter 01, ''LIMITATIONS.''
- Step 8., ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES.''
- Step 11., ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES.''

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.

AD Requirements

This AD retains some of the AFM revisions required by AD 2020–05–12, as listed under the Related Service Information under 1 CFR part 51 section of this final rule.

For Model GVII–G500 airplanes, this AD also requires revising the following sections of the existing AFM to include more restrictive limitations and procedures.

- ''Wind Conditions'' of Section 01–02–10: ''Runway, Slope, and Wind Conditions,'' of Chapter 01, ''LIMITATIONS.''
- ''Day and Night, Visual and Instrument Flight Rules'' of Section 01–03–10: ''Types of Airplane Operations Permitted,'' of Chapter 01, ''LIMITATIONS.''

• ''Approach Speed'' of Section 01–03–40: ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS.''
• Section 01–22–10: ''Autothrottle,'' of Chapter 01, ''LIMITATIONS.''
• ''WARNING'' information preceding ''Approach/Landing Airspeeds'' of Section 02–05–50: ''Landing,'' of Chapter 02, ''NORMAL OPERATIONS.''
• ''Introduction'' and ''Example'' sections of Section 05–11–10: ''Threshold Speeds'' of Chapter 05, ''PERFORMANCE.''

For Model GVII–G600 airplanes, this AD also requires adding or replacing the following sections of the existing AFM to include more restrictive limitations and procedures.

• ''Wind Conditions'' of Section 01–02–10: ''Runway, Slope, and Wind Conditions,'' of Chapter 01, ''LIMITATIONS.''
• ''Day and Night, Visual and Instrument Flight Rules'' of Section 01–03–10: ''Types of Airplane Operations Permitted,'' of Chapter 01, ''LIMITATIONS.''
• ''Approach Speed'' of Section 01–03–40: ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS.''
• Section 01–22–10: ''Autothrottle,'' of Chapter 01, ''LIMITATIONS.''
• ''WARNING'' information preceding ''Approach/Landing Airspeeds'' of Section 02–05–50: ''Landing,'' of Chapter 02, ''NORMAL OPERATIONS.''
• ''Introduction'' and ''Example'' sections of Section 05–11–10: ''Threshold Speeds'' of Chapter 05, ''PERFORMANCE.''

Interim Action

The FAA considers this AD to be an interim action. The manufacturer is developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might consider additional rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because inappropriate alpha limiter engagement during the landing flare can limit pilot pitch authority during a critical phase of flight near the ground and could result in a high rate of descent landing with possible consequent loss of control of the airplane. Given the significance of the risk presented by this unsafe condition, it must be immediately addressed. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0511 and Project Identifier AD–2022–00397–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Sanford Proveaux, Aerospace Engineer, Certificate Management and Safety Oversight Section, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5566; email: *Sanford.Proveaux@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 120 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revision	1 work-hour × $85 per hour = $85	$0	$85	$10,200

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, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–05–12, Amendment 39–19860 (85 FR 14562, March 13, 2022); and

■ b. Adding the following new AD:

2022–10–05 Gulfstream Aerospace Corporation: Amendment 39–22043; Docket No. FAA–2022–0511; Project Identifier AD–2022–00397–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 9, 2022.

(b) Affected ADs

This AD replaces AD 2020–05–12, Amendment 39–19860 (85 FR 14562, March 13, 2020) (AD 2020–05–12).

(c) Applicability

This AD applies to all Gulfstream Aerospace Corporation Model GVII–G500 and GVII–G600 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by reports of two landing incidents in which the alpha limiter engaged in the landing flare in unstable air, resulting in high rate of descent landings and damage to the airplanes. The FAA is issuing this AD to address inappropriate alpha limiter engagement during the landing flare, which can limit pilot pitch authority during a critical phase of flight near the ground, and result in a high rate of descent landing with possible consequent loss of control of the airplane on landing.

(f) Compliance

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

(g) Retained Requirements for Certain AFM Revisions for GVII–G500, With Revised Paragraph References

This introductory text to paragraph (g) restates the requirements of the introductory text to paragraph (g) of AD 2020–05–12, with revised paragraph references. For Model GVII–G500 airplanes: Within 5 days after March 13, 2020 (the effective date of AD 2020–05–12), revise the existing airplane flight manual (AFM) for your airplane to incorporate the information specified in paragraphs (g)(1) through (4) of this AD.

(1) This paragraph (g)(1) restates the information in paragraph (g)(3) of AD 2020–05–12, with no changes. Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS,'' of the Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020.

(2) This paragraph (g)(2) restates the information in paragraph (g)(4) of AD 2020–05–12, with no changes. Step 5. of Section 01–34–40, ''Takeoff and Landing Data (TOLD),'' of Chapter 01, ''LIMITATIONS,'' of the Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020.

(3) This paragraph (g)(3) restates the information in paragraph (g)(6) of AD 2020–05–12, with no changes. Step 11. ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES,'' of the Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020.

(4) This paragraph (g)(4) restates the information in paragraph (g)(7) of AD 2020–05–12, with no changes. Step 8. ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES,'' of the Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020.

(h) Retained Requirements for Certain AFM Revisions for GVII–G600, With Revised Paragraph References

This introductory text to paragraph (h) restates the requirements of the introductory text to paragraph (h) of AD 2020–05–12, with revised paragraph references. For Model GVII–G600 airplanes: Within 5 days after March 13, 2020 (the effective date of AD 2020–05–12), revise the existing AFM for your airplane to incorporate the information specified in paragraphs (h)(1) through (4) of this AD.

(1) This paragraph (h)(1) restates the information in paragraph (h)(3) of AD 2020–05–12, with no changes. Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS,'' of the Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020.

(2) This paragraph (h)(2) restates the information in paragraph (h)(4) of AD 2020–05–12, with no changes. Steps 3. and 4. of Section 01–34–40, ''Takeoff and Landing Data (TOLD),'' of Chapter 01, ''LIMITATIONS,'' of the Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020.

(3) This paragraph (h)(3) restates the information in paragraph (h)(6) of AD 2020–05–12, with no changes. Step 11., ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES,'' of the Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020.

(4) This paragraph (h)(4) restates the information in paragraph (h)(7) of AD 2020–05–12, with no changes. Step 8., ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES,'' of the Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020.

(i) New Requirements: AFM Revision for GVII–G500

For Model GVII–G500 airplanes: Within 3 days after the effective date of this AD, revise the existing AFM for your airplane as specified in paragraphs (i)(1) through (6) of this AD.

(1) Replace the information in ''Wind Conditions'' of Section 01–02–10: ''Runway, Slope, and Wind Conditions,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 1 to paragraph (i)(1) of this AD.

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Figure 1 to paragraph (i)(1) – *Section 01-02-10: Runway, Slope, and Wind Conditions*

01-02-10: Runway, Slope, and Wind Conditions

3. Wind Conditions

a. The maximum wind speed for landing (including gusts) is 15 knots.

b. The maximum wind gust for landing is 5 knots.

c. Maximum tailwind component approved for takeoff and landing: 10 knots

d. When operating in a flight control law mode other than normal (i.e., alternate, direct, or backup), maximum crosswind component for landing: 10 knots

e. Maximum tailwind component for landing with flaps 10° or less is zero knots.

(2) Replace the information in ''Day and Night, Visual and Instrument Flight Rules'' of Section 01–03–10: ''Types of Airplane Operations Permitted,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 2 to paragraph (i)(2) of this AD.

Figure 2 to paragraph (i)(2) – *Section 01-03-10: Types of Airplane Operations Permitted*

01-03-10: Types of Airplane Operations Permitted

2. Day and Night, Visual and Instrument Flight Rules

a. All approaches must be stabilized by 1000 ft AGL, including visual maneuvers.

b. Vertical guidance from an ILS or FMS-based approach is required for night landings.

(3) Replace the information in ''Approach Speed'' of Section 01–03–40: ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 3 to paragraph (i)(3) of this AD.

Figure 3 to paragraph (i)(3) – *Section 01-03-40: Airspeed Limitations*

01-03-40: Airspeed Limitations

15. Approach Speed

a. Approach speed additives (Flaps 39) are half the steady state wind plus the gust increment up to a maximum additive of 20 knots.

b. Minimum approach speed during normal operations is V_{REF} + 10 knots, unless otherwise specified in a non-normal procedure.

c. Approach Speed shall be maintained to the runway threshold and shall be used to determine landing performance except for abnormal flap approaches. Abnormal flap approaches must comply with the procedures in section 03-12-10: Zero Flaps or Partial Flaps Landings.

(4) To Section 01–22–10: ''Autothrottle,'' of Chapter 01, ''LIMITATIONS,'' add the information in figure 4 to paragraph (i)(4) of this AD.

Figure 4 to paragraph (i)(4) – *Section 01-22-10: Autothrottle*

01-22-10: Autothrottle

2. Use of the Autothrottle for approach and landing is required during normal operations.

Note

Pilot will physically guard the throttles until touchdown, and override or disconnect the autothrottle if performance is not as expected.

(5) Replace the ''WARNING'' information preceding ''Approach/Landing Airspeeds'' of Section 02–05–50: ''Landing,'' of Chapter 02, ''NORMAL OPERATIONS,'' with the information in figure 5 to paragraph (i)(5) of this AD.

Figure 5 to paragraph (i)(5) – *Section 02-05-50: Landing*

02-05-50: Landing

WARNING

EXCEPT AS REQUIRED IN AN EMERGENCY OR AS DIRECTED BY A NON-NORMAL PROCEDURE, MINIMUM APPROACH SPEED IS V_{REF} +10. APPROACH SPEED SHALL BE MAINTAINED TO THE THRESHOLD AND SHALL BE USED TO DETERMINE LANDING DISTANCE.

4. Approach/Landing Airspeeds ..... Verify

(6) Replace the ''Introduction'' and ''Examples'' sections of Section 05–11–10: ''Threshold Speeds'' of Chapter 05, ''PERFORMANCE,'' with the information in figure 6 to paragraph (i)(6) of this AD.

Figure 6 to paragraph (i)(6) – *Section 05-11-10: Threshold Speeds*

05-11-10: Threshold Speeds

Introduction

1. Threshold speeds, V_{REF}, for landing distance are shown for normal flap setting 39° in Figure 1. Threshold Speed for Landing Distance, Flaps 39°, Wing Anti-Ice OFF And ON for Wing Anti-Ice OFF and ON operations. Abnormal flap settings 20° and 10° threshold speeds for Wing Anti-Ice OFF and ON conditions are shown in Figure 2. Threshold Speed for Landing Distance, Flaps 20°, Wing Anti-Ice OFF And ON and Figure 3. Threshold Speed for Landing Distance, Flaps 10°, Wing Anti-Ice OFF And ON. For the abnormal flap setting 0°, threshold speeds shown in Figure 4. Threshold Speed for Landing Distance, Flaps 0°, Wing Anti-Ice ON are effective for Wing Anti-Ice ON operations.
2. Normally, landings will be conducted only at the landing flap setting of 39°. Additional charts are provided for reduced flap settings to be used when an abnormal landing at a reduced flap setting is required. The landing threshold speeds shown are effective throughout the certified weight, temperature and altitude range of the airplane.

WARNING

EXCEPT AS REQUIRED IN AN EMERGENCY OR AS DIRECTED BY A NON-NORMAL PROCEDURE, MINIMUM APPROACH SPEED IS V_{REF} +10. APPROACH SPEED SHALL BE MAINTAINED TO THE THRESHOLD AND SHALL BE USED TO DETERMINE LANDING DISTANCE.

CAUTION

TIRESPEED LIMITATIONS WILL BE EXCEEDED IF TOUCHDOWN IS MADE IN EXCESS OF 195 KNOTS GROUNDSPEED.

Note

Landing distance in 05-11-30: Landing Distance and maximum landing weight 05-11-20: Tire Speed and BKE Limited Maximum Landing Weight shall be calculated utilizing planned speed at the threshold.

Examples

1. Determine the final approach and threshold speeds for landing at a normal flap (39°) setting.
   - **a. Given:**
     - Landing Gross Weight = 58,000 pounds (26,308 kg)
     - Airport Pressure Altitude = 2000 feet
   - **b. Solution:**
     - Threshold Speed (V_{REF}) = 125 KIAS
     - Final Approach Speed (V_{REF} +10 KIAS) = 135 KIAS

(j) New Requirements: AFM Revision for GVII–G600

For Model GVII–G600 airplanes: Within 3 days after the effective date of this AD, revise the existing AFM for your airplane as specified in paragraphs (j)(1) through (6) of this AD.

(1) Replace the information in ''Wind Conditions'' of Section 01–02–10: ''Runway, Slope, and Wind Conditions,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 7 to paragraph (j)(1) of this AD.

Figure 7 to paragraph (j)(1) – *Section 01-02-10: Runway, Slope, and Wind Conditions*

01-02-10: Runway, Slope, and Wind Conditions

3. Wind Conditions

a. The maximum wind speed for landing (including gusts) is 15 knots.

b. The maximum wind gust for landing is 5 knots.

c. Maximum tailwind component approved for takeoff and landing: 10 knots

d. When operating in a flight control law mode other than normal (i.e., alternate, direct, or backup), maximum crosswind component for landing: 10 knots

e. Maximum tailwind component for landing with flaps 10° or less is zero knots.

(2) Replace the information in ''Day and Night, Visual and Instrument Flight Rules'' of Section 01–03–10: ''Types of Airplane Operations Permitted,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 8 to paragraph (j)(2) of this AD.

Figure 8 to paragraph (j)(2) – *Section 01-03-10: Types of Airplane Operations Permitted*

01-03-10: Types of Airplane Operations Permitted

2. Day and Night, Visual and Instrument Flight Rules

a. All approaches must be stabilized by 1000 ft AGL, including visual maneuvers.

b. Vertical guidance from an ILS or FMS-based approach is required for night landings.

(3) Replace the information in ''Approach Speed'' of Section 01–03–40: ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS,'' with the information in figure 9 to paragraph (j)(3) of this AD.

Figure 9 to paragraph (j)(3) – *Section 01-03-40: Airspeed Limitations*

01-03-40: Airspeed Limitations

15. Approach Speed

a. Approach speed additives (Flaps 39) are half the steady state wind plus the gust increment up to a maximum additive of 20 knots.

b. Minimum approach speed during normal operations is V_{REF} + 10 knots, unless otherwise specified in a non-normal procedure.

c. Approach Speed shall be maintained to the runway threshold and shall be used to determine landing performance except for abnormal flap approaches. Abnormal flap approaches must comply with the procedures in section 03-12-10: Zero Flaps or Partial Flaps Landings.

(4) To Section 01–22–10: ''Autothrottle,'' of Chapter 01, ''LIMITATIONS,'' add the information in figure 10 to paragraph (j)(4) of this AD.

Figure 10 to paragraph (j)(4) – *Section 01-22-10: Autothrottle*

01-22-10: Autothrottle

2. Use of the Autothrottle for approach and landing is required during normal operations.

Note

Pilot will physically guard the throttles until touchdown, and override or disconnect the autothrottle if performance is not as expected.

(5) Replace the ''WARNING'' information preceding ''Approach/Landing Airspeeds'' of Section 02–05–50: ''Landing,'' of Chapter 02, ''NORMAL OPERATIONS,'' with the information in figure 11 to paragraph (j)(5) of this AD.

Figure 11 to paragraph (j)(5) – *Section 02-05-50: Landing*

02-05-50: Landing

WARNING

EXCEPT AS REQUIRED IN AN EMERGENCY OR AS DIRECTED BY A NON-NORMAL PROCEDURE, MINIMUM APPROACH SPEED IS V_{REF} +10. APPROACH SPEED SHALL BE MAINTAINED TO THE THRESHOLD AND SHALL BE USED TO DETERMINE LANDING DISTANCE.

4. Approach/Landing Airspeeds ..... Verify

(6) Replace the ''Introduction'' and ''Examples'' sections of Section 05–11–10: ''Threshold Speeds'' of Chapter 05, ''PERFORMANCE,'' with the information in figure 12 to paragraph (j)(6) of this AD.

Figure 12 to paragraph (j)(6) – *Section 05-11-10: Threshold Speeds*

05-11-10: Threshold Speeds

Introduction

1. Threshold speeds, V_{REF}, for landing distance are shown for normal flap setting 39° in Figure 1. Threshold Speed for Landing Distance, Flaps 39°, Wing Anti-Ice OFF And ON for Wing Anti-Ice OFF and ON operations. Abnormal flap settings 20° and 10° threshold speeds for Wing Anti-Ice OFF and ON conditions are shown in Figure 2. Threshold Speed for Landing Distance, Flaps 20°, Wing Anti-Ice OFF And ON and Figure 3. Threshold Speed for Landing Distance, Flaps 10°, Wing Anti-Ice OFF And ON. For the abnormal flap setting 0°, threshold speeds shown in Figure 4. Threshold Speed for Landing Distance, Flaps 0°, Wing Anti-Ice ON are effective for Wing Anti-Ice ON operations.
2. Normally, landings will be conducted only at the landing flap setting of 39°. Additional charts are provided for reduced flap settings to be used when an abnormal landing at a reduced flap setting is required. The landing threshold speeds shown are effective throughout the certified weight, temperature and altitude range of the airplane.

WARNING

EXCEPT AS REQUIRED IN AN EMERGENCY OR AS DIRECTED BY A NON-NORMAL PROCEDURE, MINIMUM APPROACH SPEED IS V_{REF} +10. APPROACH SPEED SHALL BE MAINTAINED TO THE THRESHOLD AND SHALL BE USED TO DETERMINE LANDING DISTANCE.

CAUTION

TIRESPEED LIMITATIONS WILL BE EXCEEDED IF TOUCHDOWN IS MADE IN EXCESS OF 195 KNOTS GROUNDSPEED.

NOTE

Landing distance in 05-11-30: Landing Distance and maximum landing weight 05-11-20: Tire Speed and BKE Limited Maximum Landing Weight shall be calculated utilizing planned speed at the threshold.

Examples

Determine the final approach and threshold speeds for landing at a normal flap (39°) setting.

Given:

- Landing Gross Weight = 58,000 pounds (26,308 kg)
- Airport Pressure Altitude = 2000 feet

Solution:

- Threshold Speed (V_{REF}) = 111 KIAS
- Final Approach Speed (V_{REF} +10 KIAS) = 121 KIAS

BILLING CODE 4910–13–C

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) AMOC 7A0–22–06968, dated April 29, 2022, was approved as an AMOC for the requirements for AD 2020–05–12, and is approved as an AMOC for the requirements of paragraphs (g) and (h) of this AD. Other AMOCs previously issued for the requirements of AD 2020–05–12 are not approved as an AMOC for the requirements of this AD.

(l) Related Information

For more information about this AD, contact Sanford Proveaux, Aerospace Engineer, Certificate Management and Safety Oversight Section, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5566; email: *Sanford.Proveaux@faa.gov*.

(m) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on March 13, 2020 (85 FR 14562, March 13, 2020).

(i) Gulfstream GVII–G500 Airplane Flight Manual, GAC–AC–GVII–G500–OPS–0001, Revision 5, dated March 3, 2020.

(A) Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS.''

(B) Step 8., ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES.''

(C) Step 11., ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES.''

(D) Step 15., ''Approach Speed,'' of Section 01–03–40, ''Airspeed Limitations,'' of Chapter 01, ''LIMITATIONS.''

(ii) Gulfstream GVII–G600 Airplane Flight Manual, GAC–AC–GVII–G600–OPS–0001, Revision 3, dated March 3, 2020.

(A) Section 01–27–10, ''Normal Control Laws,'' of Chapter 01, ''LIMITATIONS.''

(B) Steps 3. and 4. of Section 01–34–40, ''Takeoff and Landing Data (TOLD),'' of Chapter 01, ''LIMITATIONS.''

(C) Step 8., ''Final Approach Fix,'' of Section 04–08–40, ''One Engine Inoperative Landing Procedure,'' of Chapter 04, ''EMERGENCY PROCEDURES.''

(D) Step 11., ''Landing,'' of Section 03–12–10, ''Zero Flaps or Partial Flaps Landings,'' of Chapter 03, ''ABNORMAL PROCEDURES.''

(4) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/customer-support*.

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

(6) 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 May 2, 2022.

Ross Landes,

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

[FR Doc. 2022–09925 Filed 5–5–22; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0129; Airspace Docket No. 22–AGL–8]

RIN 2120–AA66

Amendment of Class E Airspace; Marshall, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Marshall, MI. This action as the result of an airspace review conducted as part of the decommissioning of the Litchfield very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Brooks Field, Marshall, MI, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 11358; March 1, 2022) for Docket No. FAA–2022–0129 to amend the Class E airspace at Marshall, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES**

section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.3-mile (decreased from a 6.5-mile) radius of Brooks Field, Marshall, MI; removes the city associated with the airport in the header to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters; and removes the exclusionary language from the airspace legal description as it is not required.

This action is due to an airspace review conducted as part of the decommissioning of the Litchfield VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MI E5 Marshall, MI [Amended]

Brooks Field, MI

(Lat. 42°15′04″ N, long. 84°57′20″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Brooks Field.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09677 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0163; Airspace Docket No. 22–ACE–7]

RIN 2120–AA66

Amendment of Class E Airspace; Hugoton, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Hugoton, KS. This action as the result of an airspace review conducted as part of the decommissioning of the Hugoton non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Hugoton Municipal Airport, Hugoton, KS, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 12001; March 3, 2022) for Docket No. FAA–2022–0163 to amend the Class E airspace at Hugoton, KS. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021,

which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface within a 6.5-mile (reduced from a 7.2-mile) radius of Hugoton Municipal Airport, Hugoton, KS; removes the Hugoton NDB and associated extension from the airspace legal description; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review conducted as part of the decommissioning of the Hugoton NDB which provided navigation information for the instrument procedures this airport.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE KS E5 Hugoton, KS [Amended]

Hugoton Municipal Airport, KS
(Lat. 37°09′48″ N, long. 101°22′14″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Hugoton Municipal Airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09676 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0164; Airspace Docket No. 22–ACE–8]

RIN 2120–AA66

Amendment of Class E Airspace; Jefferson, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Jefferson, IA. This action as the result of an airspace review conducted as part of the decommissioning of the Jefferson non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the

Class E airspace extending upward from 700 feet above the surface at Jefferson Municipal Airport, Jefferson, IA, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 12000; March 3, 2022) for Docket No. FAA–2022–0164 to amend the Class E airspace at Jefferson, IA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface within a 6.4-mile (increased from a 6.3-mile) radius of Jefferson Municipal Airport, Jefferson, IA; removes the Jefferson NDB and associated extension from the airspace legal description; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review conducted as part of the decommissioning of the Jefferson NDB which provided navigation information for the instrument procedures this airport.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE IA E5 Jefferson, IA [Amended]

Jefferson Municipal Airport, IA
(Lat. 42°00′35″ N, long. 94°20′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Jefferson Municipal Airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09678 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0130; Airspace Docket No. 22–AGL–9]

RIN 2120–AA66

Amendment of Class E Airspace; Ashtabula, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Ashtabula, OH. This action as the result of an airspace review conducted as part of the decommissioning of the Jefferson very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The name and geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Northeast Ohio Regional Airport, Ashtabula, OH, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 11364; March 1, 2022) for Docket No. FAA–2022–0130 to amend the Class E airspace at Ashtabula, OH. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Northeast Ohio Regional Airport, Ashtabula, OH, by adding an extension 2 miles each side of the 259° bearing from the airport extending from the 6.5-mile radius of the airport to 9.6 miles west of the airport; removes the city associated with Ashtabula County Medical Center, contained within the airspace legal description, in the header to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters; and updates the name (previously Ashtabula County Airport), state, and geographic coordinates of Northeast Ohio Regional Airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Jefferson VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL OH E5 Ashtabula, OH [Amended]

Northeast Ohio Regional Airport, OH
(Lat. 41°46′40″ N, long. 80°41′48″ W)
Ashtabula County Medical Center, OH, Point in Space Coordinates
(Lat. 41°52′47″ N, long. 80°46′42″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Northeast Ohio Regional Airport, and within 2 miles each side of the 259° bearing from the Northeast Ohio Regional Airport extending from the 6.5-mile radius to 9.6 miles west of the Northeast Ohio Regional Airport, and within a 6-mile radius of the Point in Space serving the Ashtabula County Medical Center.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09675 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2021–0074; Airspace Docket No. 20–ANE–5]

RIN 2120–AA66

Amendment of Restricted Areas R–4102A and R–4102B; Fort Devens, MA

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action modifies restricted areas R–4102A and R–4102B at Fort Devens, MA, by amending the

boundaries of the areas to align with the boundaries of the Fort Devens' installation property; and by changing the time of designation to reflect actual usage of the airspace.

DATES: Effective date: 0901 UTC, July 14, 2022.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes restricted area airspace at Fort Devens, MA, to enhance aviation safety and accommodate essential U.S. Army training activities.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0074 in the **Federal Register** (86 FR 17555; April 5, 2021), proposing to modify restricted areas R–4102A and R–4102B at Fort Devens, MA, to update the time of designation and the lateral boundaries of the areas. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. One comment was received from an individual commenter.

Discussion of Comment

The commenter expressed concern about FAA's determination of ''no significant impact'' with regard to this action. The commenter likened it to FAA's decision in the case of Moore Army Airfield in which the commenter stated the 60 days comment period was waived. Moreover, the commenter stated that the public lacked the benefit of a noise impact study. Moore Airfield was closed during the 1990s and is now used for auto racing and for state police training. Finally, the commenter stated that they ''disagree with lifting the restrictions that are currently over Oxbow Wildlife Refuge'' as ''[p]ropeller planes are dumping noise and leaded aviation fuel emissions.''

In this case, the Environmental Assessment (EA) and Finding of No Significant Impact (FNSI) were available for review and comment for 30 days, beginning June 22, 2018, and ending July 23, 2018. Copies of the EA and Draft FNSI were made available on the official Fort Devens website and printed copies were also made available at four local libraries: The Ayer Public Library, the Hazen Memorial Library in Shirley, the Harvard Public Library, and the Thayer Memorial Library in Lancaster. The Army received responses from the Massachusetts Historical Commission and Fitchburg Municipal Airport during the 30-day public review period. The Army carefully read and considered all comments received. Moreover, the EA's section on Biological Resources found that although biological communities are found in the surrounding areas, no noise impacts are anticipated on these communities because no changes are proposed to the types of aircraft or types and number of operations conducted within the airspace.

With regard to the commenter's final point, the current restricted area configuration does infringe on the southernmost part of the Refuge. However, this area is not available for use by the military for environmental reasons. Therefore, there is no justification for retaining restricted airspace over that location. Restricted areas are only designated when necessary to contain and segregate activities that would pose a hazard to aviation rather than address environmental concerns. The Oxbow Refuge is identified on Visual Flight Rules (VFR) aeronautical charts for pilot awareness. An advisory note on the chart requests that pilots maintain a minimum flight altitude of 2,000 feet above the ground if overflying the Refuge and similar sensitive areas.

The Rule

This action amends 14 CFR part 73 by modifying the time of designation, and the boundaries of restricted areas R–4102A and R–4102B at Fort Devens, MA. The current time of designation is ''0800 to 2200 Saturday, local time; other times by NOTAM issued 24 hours in advance.'' This designation does not reflect the actual routine daily use of the airspace necessary to meet the training requirements at Fort Devens. The FAA is amending the time of designation to read: ''Intermittent, 0730 to 2200 local time, daily; other times by NOTAM issued 24 hours in advance.'' This change provides more accurate information to the aviation community about the current routine use of the airspace, and it eliminates the administrative workload now required to issue daily NOTAMs to activate the restricted areas.

The FAA is also modifying the boundaries of restricted areas R–4102A and R–4102B by removing sections of the restricted airspace that are not contained within the Fort Devens installation property boundaries. Additionally, this rule slightly expands the restricted areas on the northwest, northeast, and southeast sides to include small parts of the training area that are actually located within the Fort Devens installation property boundaries, but are outside of the current restricted area boundaries. Taken together, these restricted area boundary changes result in an overall reduction in the size of the restricted areas at Fort Devens. The result is improved functionality of the training area as well as increase safety during training operations.

During periods when the restricted areas are not needed by the using agency, the airspace will be returned to the controlling agency (FAA, Boston Approach Control) for access by other aviation users.

Regulatory Notices and Analyses

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 Department of Transportation (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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of modifying restricted areas R–4102A and R–4102B at Fort Devens, MA, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F,

Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study for this rulemaking action. On May 31, 2019, in accordance with FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* Paragraph 8–2, *Adoption of Other Agencies' NEPA Documents,* the FAA finalized its adoption Environmental Assessment of the Army's Establishment of Restricted Area Airspace (R-) 4102A/B at U.S. Army Garrison Fort Devens, Final Environmental Assessment of *Airspace Change Proposal at U.S. Army Garrison Fort Devens, Massachusetts.* The Army's Final EA analyzed the potential environmental impacts of the proposed establishment of additional restricted area airspace in support of the Army's training exercises. The additional restricted area airspace would lower the risk of encountering non-participating aircraft during those exercises. No changes to the types of aircraft or types and number of operations conducted within the airspace were proposed.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.41 Massachusetts [Amended]

■ 2. Section 73.38 is amended as follows:

R–4102A Fort Devens, MA [Amended]

Boundaries. Beginning at lat. 42°31′11″ N, long. 71°38′29″ W; to lat. 42°30′55″ N, long. 71°37′51″ W; to lat. 42°30′12″ N, long. 71°38′05″ W; to lat. 42°29′38″ N, long. 71°37′41″ W; to lat. 42°28′21″ N, long. 71°39′14″ W; to lat. 42°28′11″ N, long. 71°39′32″ W; to lat. 42°28′11″ N, long. 71°39′38″ W; to lat. 42°28′15″ N, long. 71°39′45″ W; to lat. 42°28′25″ N, long. 71°40′08″ W; to lat. 42°28′54″ N, long. 71°41′00″ W; to lat. 42°29′08″ N, long. 71°41′06″ W; to lat. 42°29′52″ N, long. 71°41′08″ W; to lat. 42°30′17″ N, long. 71°41′29″ W; to lat. 42°30′19″ N, long. 71°41′19″ W; to lat. 42°30′37″ N, long. 71°40′30″ W; to lat. 42°30′43″ N, long. 71°40′17″ W; to lat. 42°30′52″ N, long. 71°40′14″ W; to lat. 42°30′54″ N, long. 71°40′10″ W; to lat. 42°30′53″ N, long. 71°40′02″ W; to lat. 42°30′48″ N, long. 71°39′57″ W; to lat. 42°30′47″ N, long. 71°39′45″ W; to lat. 42°30′55″ N, long. 71°39′31″ W; to lat. 42°30′58″ N, long. 71°39′18″ W; to lat. 42°30′57″ N, long. 71°39′09″ W; to lat. 42°30′52″ N, long. 71°38′42″ W; to lat. 42°30′58″ N, long. 71°38′33″ W; to lat. 42°31′06″ N, long. 71°38′37″ W;

thence to the point of beginning.

Designated altitudes. Surface to, but not including, 2000 feet MSL.

Time of designation. Intermittent, 0730–2200 local time, daily; other times by NOTAM issued 24 hours in advance.

Controlling agency. FAA, Boston Approach Control.

Using agency. Commander, U.S. Army Garrison, Fort Devens, MA.

R–4102B Fort Devens, MA [Amended]

Boundaries. Beginning at lat. 42°31′11″ N, long. 71°38′29″ W; to lat. 42°30′55″ N, long. 71°37′51″ W; to lat. 42°30′12″ N, long. 71°38′05″ W; to lat. 42°29′38″ N, long. 71°37′41″ W; to lat. 42°28′21″ N, long. 71°39′14″ W; to lat. 42°28′11″ N, long. 71°39′32″ W; to lat. 42°28′11″ N, long. 71°39′38″ W; to lat. 42°28′15″ N, long. 71°39′45″ W; to lat. 42°28′25″ N, long. 71°40′08″ W; to lat. 42°28′54″ N, long. 71°41′00″ W; to lat. 42°29′08″ N, long. 71°41′06″ W; to lat. 42°29′52″ N, long. 71°41′08″ W; to lat. 42°30′17″ N, long. 71°41′29″ W; to lat. 42°30′19″ N, long. 71°41′19″ W; to lat. 42°30′37″ N, long. 71°40′30″ W; to lat. 42°30′43″ N, long. 71°40′17″ W; to lat. 42°30′52″ N, long. 71°40′14″ W; to lat. 42°30′54″ N, long. 71°40′10″ W; to lat. 42°30′53″ N, long. 71°40′02″ W; to lat. 42°30′48″ N, long. 71°39′57″ W; to lat. 42°30′47″ N, long. 71°39′45″ W; to lat. 42°30′55″ N, long. 71°39′31″ W; to lat. 42°30′58″ N, long. 71°39′18″ W; to lat. 42°30′57″ N, long. 71°39′09″ W; to lat. 42°30′52″ N, long. 71°38′42″ W; to lat. 42°30′58″ N, long. 71°38′33″ W; to lat. 42°31′06″ N, long. 71°38′37″ W;

thence to the point of beginning.

Designated altitudes. 2000 feet MSL to 3995 feet MSL.

Time of designation. Intermittent, 0730–2200 local time, daily; other times by NOTAM issued 24 hours in advance.

Controlling agency. FAA, Boston Approach Control.

Using agency. Commander, U.S. Army Garrison, Fort Devens, MA.

Issued in Washington, DC, on May 3, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09921 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

RAILROAD RETIREMENT BOARD

20 CFR Part 220

RIN 3220–AB77

Consultative Examinations

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board amends its regulations concerning consultative examinations used in adjudication of claims for disability annuities. The amendment permits psychological and psychiatric consultative examinations to be conducted through the use of video teleconferencing technology. The amendment allows the remote conduct of examinations where physical contact is not required and facilitates medical evaluations when physical proximity is not feasible.

DATES: This regulation is effective May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Marguerite P. Dadabo, (312) 751–4945, TTD (312) 751–4701, *Marguerite.Dadabo@rrb.gov.*

SUPPLEMENTARY INFORMATION: The Railroad Retirement Board (Board) amends its disability regulations to allow video teleconferencing technology (VTT) to be used to conduct a psychological or a psychiatric consultative examination in a case where such technology permits proper evaluation of a claimant. A VTT consultative examination is an examination conducted through a telecommunications system that allows the examining physician or psychologist and the claimant to see and hear each other for the purpose of communication in real time. A VTT consultative examination must comply with all requirements for consultative examinations in subpart G of part 220 of the Board's regulations, 20 CFR part 220, subpart G. In addition, the following requirements must be followed if a VTT consultative examination is used. The examining

physician or psychologist must be currently licensed in the state in which the provider practices.

The examining physician or psychologist must have the training and experience to perform the type of examination requested. The examining physician or psychologist must have access to VTT, and the claimant must live in the same state in which the provider practices. The claimant shall have the right to refuse a VTT consultative examination without penalty.

A proposed rule was published on February 3, 2022, and comments were requested by April 4, 2022, 87 FR 6094, February 3, 2022. One comment was submitted. While expressing support for the proposed change as ''a positive change by the agency to embrace the technological transformation,'' the commenter quoted the proposed sentence in § 220.57(c)(2), which states that ''[t]he examining physician or psychologist has the training and experience to perform the type of examination requested'' and commented that this statement does not quantify the required minimum years of experience for the examining physician or psychologist. The commenter explained that unless years of experience are specified, any physician with just 1 prior experience of performing such kind of examination will be qualified and suggested that the minimum number of years of experience be added to the clause to avoid any confusion and make the rule clear. The Board considered the commenter's suggestion, but decided not to quantify a minimum number of years of experience to use VTT as the examining physician or psychologist would be licensed and in good standing in the state in which he or she practices and would have the training and experience necessary to perform the type of examination or test required.

No changes were made in the proposed rule, which is now being published as a final regulation.

Regulatory Requirements

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563.

Executive Order 13132 (Federalism)

This final rule will not have substantial direct effects 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. Therefore, in accordance with section 6 of Executive Order 13132, the Board believes that this final rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Regulatory Flexibility Act

We certify that this final rule would not have a significant economic impact on a substantial number of small entities because the final rule affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, does not require OMB approval under the Paperwork Reduction Act.

List of Subjects in 20 CFR Part 220

Disability benefits, Railroad employees, Railroad retirement.

For the reasons discussed in the preamble, the Railroad Retirement Board amends 20 CFR part 220 as follows:

PART 220—DETERMINING DISABILITY

■ 1. The authority citation for part 220 continues to read as follows:

Authority: 45 U.S.C. 231a; 45 U.S.C. 231f.

■ 2. Amend § 220.57 by adding paragraph (c) to read as follows:

§ 220.57 Types of purchased examinations and selection of sources.

* * * * *

(c) *Use of video teleconferencing technology.* Video teleconferencing technology (VTT) may be used for a psychological or a psychiatric consultative examination provided that the following requirements are met:

(1) The examining physician or psychologist is currently state-licensed in the state in which the provider practices;

(2) The examining physician or psychologist has the training and experience to perform the type of examination requested;

(3) The examining physician or psychologist has access to video teleconferencing technology;

(4) The examining physician or psychologist is permitted to perform the exam in accordance with state licensing laws and regulations;

(5) The protocol for the examination does not require physical contact;

(6) The claimant has the right to refuse a VTT examination without penalty; and

(7) The VTT examination complies with all requirements in this subpart governing consultative examinations.

Dated: May 4, 2022.

For the Board.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2022–09905 Filed 5–6–22; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 85

[Docket No. OLP 172]

Civil Monetary Penalties Inflation Adjustments for 2022

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice is adjusting for inflation the civil monetary penalties assessed or enforced by components of the Department, in accordance with the provisions of the Bipartisan Budget Act of 2015, for penalties assessed after May 9, 2022 with respect to violations occurring after November 2, 2015.

DATES: This rule is effective May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Statutory Process for Implementing Annual Inflation Adjustments

Section 701 of the Bipartisan Budget Act of 2015, Public Law 114–74 (Nov. 2, 2015) (''BBA''), 28 U.S.C. 2461 note, substantially revised the prior provisions of the Federal Civil Monetary

Penalties Inflation Adjustment Act of 1990, Public Law 101–410 (the ''Inflation Adjustment Act''), and substituted a different statutory formula for calculating inflation adjustments on an annual basis.

In accordance with the provisions of the BBA, on June 30, 2016 (81 FR 42491), the Department of Justice published an interim rule (''June 2016 interim rule'') to adjust for inflation the civil monetary penalties assessed or enforced by components of the Department after August 1, 2016, with respect to violations occurring after November 2, 2015, the date of enactment of the BBA. Readers may refer to the **SUPPLEMENTARY INFORMATION** (also known as the preamble) of the Department's June 2016 interim rule for additional background information regarding the statutory authority for adjustments of civil monetary penalty amounts to take account of inflation and the Department's past implementation of inflation adjustments. The June 2016 interim rule was finalized without change by the publication of a final rule on April 5, 2019 (84 FR 13525).

After the initial adjustments in 2016, the BBA also provides for agencies to adjust their civil penalties on January 15 of each year to account for inflation during the preceding year, rounded to the nearest dollar. Accordingly, on February 3, 2017 (82 FR 9131), and on January 29, 2018 (83 FR 3944), the Department published final rules pursuant to the BBA to make annual inflation adjustments in the civil monetary penalties assessed or enforced by components of the Department after those dates, with respect to violations occurring after November 2, 2015.

The Department has continued to promulgate rules adjusting the civil money penalties for inflation thereafter. Most recently, the Department published a final rule on December 13, 2021 (86 FR 70740), to adjust the civil money penalties to account for inflation occurring since 2020.

II. Inflation Adjustments Made by This Rule

As required, the Department is publishing this final rule to adjust for 2022 the Department's current civil penalties. Under the statutory formula, the adjustments made by this rule are based on the Bureau of Labor Statistics' Consumer Price Index for October 2021. The OMB Memorandum for the Heads of Executive Departments and Agencies M–22–07 (Dec. 15, 2021) *https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-07.pdf* (last visited May 2, 2022), instructs that the applicable inflation factor for this adjustment is 1.06222.

Accordingly, this rule adjusts the civil penalty amounts in 28 CFR 85.5 by applying this inflation factor mechanically to each of the civil penalty amounts listed (rounded to the nearest dollar).

Example:

- In 2016, the Program Fraud Civil Remedies Act penalty was increased to $10,781 in accordance with the adjustment requirements of the BBA.
- For 2017, where the applicable inflation factor was 1.01636, the existing penalty of $10,781 was multiplied by 1.01636 and revised to $10,957 (rounded to the nearest dollar).
- For 2018, where the applicable inflation factor is 1.02041, the existing penalty of $10,957 was multiplied by 1.02041 and revised to $11,181 (rounded to the nearest dollar).
- Had an adjustment rule been published in 2019, where the applicable inflation factor was 1.02041, the existing penalty of $11,181 would have been multiplied by 1.02522 and revised to $11,463 (rounded to the nearest dollar).
- For the final rule in 2020 (*in which the ending 2019 penalty amounts were used as the starting penalty amounts for purposes of calculation*) the starting penalty of $11,463 was multiplied by 1.01764 and revised to $11,665 (rounded to the nearest dollar.)
- For the final rule in 2021, where the applicable inflation factor was 1.01182, the existing penalty of $11,665 was multiplied by 1.01182 and revised to $11,803 (rounded to the nearest dollar).
- For this final rule in 2022, where the applicable inflation factor is 1.06222, the existing penalty of $11,803 is multiplied by 1.06222 and revised to $12,537 (rounded to the nearest dollar).

This rule adjusts for inflation civil monetary penalties within the jurisdiction of the Department of Justice for purposes of the Inflation Adjustment Act, as amended. Other agencies are responsible for the inflation adjustments of certain other civil monetary penalties that the Department's litigating components bring suit to collect. The reader should consult the regulations of those other agencies for inflation adjustments to those penalties.

III. Effective Date of Adjusted Civil Penalty Amounts

Under this rule, the adjusted civil penalty amounts are applicable only to civil penalties assessed after May 9, 2022, with respect to violations occurring after November 2, 2015, the date of enactment of the BBA.

The penalty amounts set forth in the existing table in 28 CFR 85.5 are applicable to civil penalties assessed after August 1, 2016, and on or before the effective date of this rule, with respect to violations occurring after November 2, 2015. Civil penalties for violations occurring on or before November 2, 2015, and assessments made on or before August 1, 2016, will continue to be subject to the civil monetary penalty amounts set forth in the Department's regulations in 28 CFR parts 20, 22, 36, 68, 71, 76, and 85 as such regulations were in effect prior to August 1, 2016 (or as set forth by statute if the amount had not yet been adjusted by regulation prior to August 1, 2016).

IV. Statutory and Regulatory Analyses

A. Administrative Procedure Act

The BBA provides that, for each annual adjustment made after the initial adjustments of civil penalties in 2016, the head of an agency shall adjust the civil monetary penalties each year notwithstanding 5 U.S.C. 553. Accordingly, this rule is being issued as a final rule without prior notice and public comment, and without a delayed effective date.

B. Regulatory Flexibility Act

Only those entities that are determined to have violated Federal law and regulations would be affected by the increase in the civil penalty amounts made by this rule. A Regulatory Flexibility Act analysis is not required for this rule because publication of a notice of proposed rulemaking was not required. *See* 5 U.S.C. 603(a).

C. Executive Orders 12866 and 13563—Regulatory Review

This final rule has been drafted in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation, and in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1, General Principles of Regulation. Executive Orders 12866 and 13563 direct agencies, in certain circumstances, 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).

The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' section 3(f), and, accordingly, this rule has not been

reviewed by the Office of Management and Budget. This final rule implements the BBA by making an across-the-board adjustment of the civil penalty amounts in 28 CFR 85.5 to account for inflation since the adoption of the Department's final rule published on December 13, 2021 (86 FR 70740).

D. Executive Order 13132—Federalism

This rule will not have substantial direct effects 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. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

E. Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

G. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804.

List of Subjects in 28 CFR Part 85

Administrative practice and procedure, Penalties.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Assistant Attorney General, Office of Legal Policy, by AG Order No. 5328–2022, and for the reasons set forth in the preamble, chapter I of title 28 of the Code of Federal Regulations is amended as follows:

PART 85—CIVIL MONETARY PENALTIES INFLATION ADJUSTMENT

■ 1. The authority citation for part 85 continues to read as follows:

Authority: 5 U.S.C. 301, 28 U.S.C. 503; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321; Pub. L. 114–74, section 701, 28 U.S.C. 2461 note.

■ 2. Section 85.5 is revised to read as follows:

§ 85.5 Adjustments to penalties for violations occurring after November 2, 2015.

(a) For civil penalties assessed after May 9, 2022, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are adjusted as set forth in the seventh column of table 1 to this section.

(b) For civil penalties assessed after December 13, 2021, and on or before May 9, 2022 whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are adjusted as set forth in the sixth column of table 1 to this section. For civil penalties assessed after June 19, 2020, and on or before December 13, 2021, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are adjusted as set forth in the fifth column of table 1 to this section. For civil penalties assessed after January 29, 2018, and on or before June 19, 2020, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are those set forth in the fourth column of table 1 to this section.

(c) For civil penalties assessed on or before January 29, 2018, the civil monetary penalties provided by law within the jurisdiction of the Department are set forth in 28 CFR 85.5 (revised as of July 1, 2017).

(d) All figures set forth in table 1 to this section are maximum penalties, unless otherwise indicated.

TABLE 1 TO § 85.5

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 1/29/2018 ($)	DOJ penalty assessed after 6/19/2020 ($)	DOJ penalty assessed after 12/13/2021 [1]	DOJ penalty assessed after 5/9/2022 [2]
ATF						
18 U.S.C. 922(t)(5)	Brady Law—Nat'l Instant Criminal Check System (NICS); Transfer of firearm without checking NICS.		8,465	8,831	8,935	9,491.
18 U.S.C. 924(p)	Child Safety Lock Act; Secure gun storage or safety device, violation.		3,096	3,230	3,268	3,471.
Civil Division						
12 U.S.C. 1833a(b)(1)	Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) Violation.	28 CFR 85.3(a)(6)	1,963,870	2,048,915	2,073,133	2,202,123.
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing) (per day).	28 CFR 85.3(a)(7)	1,963,870	2,048,915	2,073,133	2,202,123.
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing)	28 CFR 85.3(a)(7)	9,819,351	10,244,577	10,365,668	11,010,620.
22 U.S.C. 2399b(a)(3)(A)	Foreign Assistance Act; Fraudulent Claim for Assistance (per act).	28 CFR 85.3(a)(8)	5,704	5,951	6,021	6,396.
31 U.S.C. 3729(a)	False Claims Act; [3] Violations	28 CFR 85.3(a)(9)	Min 11,181, Max 22,363.	Min 11,665, Max 23,331.	Min 11,803, Max 23,607.	Min 12,537, Max 25,076.
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act; Violations Involving False Claim (per claim).	28 CFR 71.3(a)	11,181	11,665	11,803	12,537.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 1/29/2018 ($)	DOJ penalty assessed after 6/19/2020 ($)	DOJ penalty assessed after 12/13/2021 [1]	DOJ penalty assessed after 5/9/2022 [2]
31 U.S.C. 3802(a)(2)	Program Fraud Civil Remedies Act; Violation Involving False Statement (per statement).	28 CFR 71.3(f)	11,181	11,665	11,803	12,537.
40 U.S.C. 123(a)(1)(A)	Federal Property and Administrative Services Act; Violation Involving Surplus Government Property (per act).	28 CFR 85.3(a)(12)	5,704	5,951	6,021	6,396.
41 U.S.C. 8706(a)(1)(B)	Anti-Kickback Act; Violation Involving Kickbacks [4] (per occurrence).	28 CFR 85.3(a)(13)	22,363	23,331	23,607	25,076.
18 U.S.C. 2723(b)	Driver's Privacy Protection Act of 1994; Prohibition on Release and Use of Certain Personal Information from State Motor Vehicle Records—Substantial Noncompliance (per day).		8,249	8,606	8,708	9,250.
18 U.S.C. 216(b)	Ethics Reform Act of 1989; Penalties for Conflict of Interest Crimes [5] (per violation).	28 CFR 85.3(c)	98,194	102,446	103,657	110,107.
41 U.S.C. 2105(b)(1)	Office of Federal Procurement Policy Act; [6] Violation by an individual (per violation).		102,606	107,050	108,315	115,054.
41 U.S.C. 2105(b)(2)	Office of Federal Procurement Policy Act; [6] Violation by an organization (per violation).		1,026,054	1,070,487	1,083,140	1,150,533.
42 U.S.C. 5157(d)	Disaster Relief Act of 1974; [7] Violation (per violation).		12,964	13,525	13,685	14,536.
Civil Rights Division (excluding immigration-related penalties)						
18 U.S.C. 248(c)(2)(B)(i)	Freedom of Access to Clinic Entrances Act of 1994 (''FACE Act''); Nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(1)(i).	16,499	17,161	17,364	18,444.
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(1)(ii).	24,748	25,820	26,125	27,750.
18 U.S.C. 248(c)(2)(B)(i)	FACE Act; Violation other than a nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(2)(i).	24,748	25,820	26,125	27,750.
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Violation other than a nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(2)(ii).	41,248	43,034	43,543	46,252.
42 U.S.C. 3614(d)(1)(C)(i)	Fair Housing Act of 1968; first violation.	28 CFR 85.3(b)(3)(i).	102,606	107,050	108,315	115,054.
42 U.S.C. 3614(d)(1)(C)(ii)	Fair Housing Act of 1968; subsequent violation.	28 CFR 85.3(b)(3)(ii).	205,211	214,097	216,628	230,107.
42 U.S.C. 12188(b)(2)(C)(i)	Americans With Disabilities Act; Public accommodations for individuals with disabilities, first violation.	28 CFR 36.504(a)(3)(i).	92,383	96,384	97,523	103,591.
42 U.S.C. 12188(b)(2)(C)(ii)	Americans With Disabilities Act; Public accommodations for individuals with disabilities subsequent violation.	28 CFR 36.504(a)(3)(ii).	184,767	192,768	195,047	207,183.
50 U.S.C. 4041(b)(3)	Servicemembers Civil Relief Act of 2003; first violation.	28 CFR 85.3(b)(4)(i).	62,029	64,715	65,480	69,554.
50 U.S.C. 4041(b)(3)	Servicemembers Civil Relief Act of 2003; subsequent violation.	28 CFR 85.3(b)(4)(ii).	124,058	129,431	130,961	139,109.
Criminal Division						
18 U.S.C. 983(h)(1)	Civil Asset Forfeiture Reform Act of 2000; Penalty for Frivolous Assertion of Claim.		Min 355, Max 7,088.	Min 370, Max 7,395.	Min 374, Max 7,482.	Min 397, Max 7,948.
18 U.S.C. 1956(b)	Money Laundering Control Act of 1986; Violation [8].		22,363	23,331	23,607	25,076.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 1/29/2018 ($)	DOJ penalty assessed after 6/19/2020 ($)	DOJ penalty assessed after 12/13/2021 [1]	DOJ penalty assessed after 5/9/2022 [2]
DEA						
21 U.S.C. 844a(a)	Anti-Drug Abuse Act of 1988; Possession of small amounts of controlled substances (per violation).	28 CFR 76.3(a)	20,521	21,410	21,663	23,011.
21 U.S.C. 961(1)	Controlled Substance Import Export Act; Drug abuse, import or export.	28 CFR 85.3(d)	71,301	74,388	75,267	79,950.
21 U.S.C. 842(c)(1)(A)	Controlled Substances Act (''CSA''); Violations of 842(a)—other than (5), (10), (16) and (17)—Prohibited acts re: controlled substances (per violation).		64,820	67,627	68,426	72,683.
21 U.S.C. 842(c)(1)(B)(i)	CSA; Violations of 842(a)(5), (10), and (17)—Prohibited acts re: controlled substances.		15,040	15,691	15,876	16,864.
21 U.S.C. 842(c)(1)(B)(ii)	SUPPORT for Patients and Communities Act; Violations of 842(b)(ii)—Failures re: opioids.		100,000 (Statutory amount of new penalty enacted 10/24/18) [11].	101,764	102,967	109,374.
21 U.S.C. 842(c)(1)(C)	CSA; Violation of 825(e) by importer, exporter, manufacturer, or distributor—False labeling of anabolic steroids (per violation).		519,439	541,933	548,339	582,457.
21 U.S.C. 842(c)(1)(D)	CSA; Violation of 825(e) at the retail level—False labeling of anabolic steroids (per violation).		1,039	1,084	1,097	1,165.
21 U.S.C. 842(c)(2)(C)	CSA; Violation of 842(a)(11) by a business—Distribution of laboratory supply with reckless disregard [9].		389,550	406,419	411,223	436,809.
21 U.S.C. 842(c)(2)(D)	SUPPORT for Patients and Communities Act; Violations of 842(a)(5), (10) and (17) by a registered manufacture or distributor of opioids. Failures re: opioids.		500,000 (Statutory amount of new penalty enacted 10/24/18) [11].	508,820	514,834	546,867.
21 U.S.C. 856(d)	Illicit Drug Anti-Proliferation Act of 2003; Maintaining drug-involved premises [10].		333,328	374,763	379,193	402,786.
Immigration-Related Penalties						
8 U.S.C. 1324a(e)(4)(A)(i)	Immigration Reform and Control Act of 1986 (''IRCA''); Unlawful employment of aliens, first order (per unauthorized alien).	28 CFR 68.52(c)(1)(i).	Min 559, Max 4,473.	Min 583, Max 4,667.	Min 590, Max 4,722.	Min 627, Max 5,016.
8 U.S.C. 1324a(e)(4)(A)(ii)	IRCA; Unlawful employment of aliens, second order (per such alien).	28 CFR 68.52(c)(1)(ii).	Min 4,473, Max 11,181.	Min 4,667, Max 11,665.	Min 4,722, Max 11,803.	Min 5,016, Max 12,537.
8 U.S.C. 1324a(e)(4)(A)(iii)	IRCA; Unlawful employment of aliens, subsequent order (per such alien).	28 CFR 68.52(c)(1)(iii).	Min 6,709, Max 22,363.	Min 6,999, Max 23,331.	Min 7,082, Max 23,607.	Min 7,523, Max 25,076.
8 U.S.C. 1324a(e)(5)	IRCA; Paperwork violation (per relevant individual).	28 CFR 68.52(c)(5)	Min 224, Max 2,236.	Min 234, Max 2,332.	Min 237, Max 2,360.	Min 252, Max 2,507.
8 U.S.C. 1324a, (note)	IRCA; Violation relating to participating employer's failure to notify of final nonconfirmation of employee's employment eligibility (per relevant individual).	28 CFR 68.52(c)(6)	Min 779, Max 1,558.	Min 813, Max 1,625.	Min 823, Max 1,644.	Min 874, Max 1,746.
8 U.S.C. 1324a(g)(2)	IRCA; Violation/prohibition of indemnity bonds (per violation).	28 CFR 68.52(c)(7)	2,236	2,332	2,360	2,507.
8 U.S.C. 1324b(g)(2)(B)(iv)(I).	IRCA; Unfair immigration-related employment practices, first order (per individual discriminated against).	28 CFR 68.52(d)(1)(viii).	Min 461, Max 3,695.	Min 481, Max 3,855.	Min 487, Max 3,901.	Min 517, Max 4,144.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 1/29/2018 ($)	DOJ penalty assessed after 6/19/2020 ($)	DOJ penalty assessed after 12/13/2021 [1]	DOJ penalty assessed after 5/9/2022 [2]
8 U.S.C. 1324b(g)(2)(B)(iv)(II).	IRCA; Unfair immigration-related employment practices, second order (per individual discriminated against).	28 CFR 68.52(d)(1)(ix).	Min 3,695, Max 9,239.	Min 3,855, Max 9,639.	Min 3,901, Max 9,753.	Min 4,144, Max 10,360.
8 U.S.C. 1324b(g)(2)(B)(iv)(III).	IRCA; Unfair immigration-related employment practices, subsequent order (per individual discriminated against).	28 CFR 68.52(d)(1)(x).	Min 5,543, Max 18,477.	Min 5,783, Max 19,277.	Min 5,851, Max 19,505.	Min 6,215, Max 20,719.
8 U.S.C. 1324b(g)(2)(B)(iv)(IV).	IRCA; Unfair immigration-related employment practices, unfair documentary practices (per individual discriminated against).	28 CFR 68.52(d)(1)(xii).	Min 185, Max 1,848.	Min 193, Max 1,928.	Min 195, Max 1,951.	Min 207, Max 2,072.
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(i).	Min 461, Max 3,695.	Min 481, Max 3,855.	Min 487, Max 3,901.	Min 517, Max 4,144.
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(iii).	Min 3,695, Max 9,239.	Min 3,855, Max 9,639.	Min 3,901, Max 9,753.	Min 4,144, Max 10,360.
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(ii).	Min 390, Max 3,116.	Min 407, Max 3,251.	Min 412, Max 3,289.	Min 438, Max 3,494.
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(iv).	Min 3,116, Max 7,791.	Min 3,251, Max 8,128.	Min 3,289, Max 8,224.	Min 3,494, Max 8,736.
FBI						
49 U.S.C. 30505(a)	National Motor Vehicle Title Identification System; Violation (per violation).	.....	1,650	1,722	1,742	1,850.
Office of Justice Programs						
34 U.S.C. 10231(d)	Confidentiality of information; State and Local Criminal History Record Information Systems—Right to Privacy Violation.	28 CFR 20.25	28,520	29,755	30,107	31,980.

[1] The figures set forth in this column represent the penalty as last adjusted by Department of Justice regulation on December 13, 2021.

[2] All figures set forth in this table are maximum penalties, unless otherwise indicated.

[3] Section 3729(a)(1) of Title 31 provides that any person who violates this section is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. 3729(a)(1) (2015). Section 3729(a)(2) permits the court to reduce the damages under certain circumstances to not less than 2 times the amount of damages which the Government sustains because of the act of that person. Id. section 3729(a)(2). The adjustment made by this regulation is only applicable to the specific statutory penalty amounts stated in subsection (a)(1), which is only one component of the civil penalty imposed under section 3729(a)(1).

[4] Section 8706(a)(1) of Title 41 provides that the Federal Government in a civil action may recover from a person that knowingly engages in conduct prohibited by section 8702 of Title 44 a civil penalty equal to twice the amount of each kickback involved in the violation and not more than $10,000 for each occurrence of prohibited conduct. 41 U.S.C. 8706(a)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (a)(1)(B), which is only one component of the civil penalty imposed under section 8706.

[5] Section 216(b) of Title 18 provides that the civil penalty should be no more than $50,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater. 18 U.S.C. 216(b) (2015). Therefore, the adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b), which is only one aspect of the possible civil penalty imposed under section 216(b).

[6] Section 2105(b) of Title 41 provides that the Attorney General may bring a civil action in an appropriate district court of the United States against a person that engages in conduct that violates section 2102, 2103, or 2104 of Title 41. 41 U.S.C. 2105(b) (2015). Section 2105(b) further provides that on proof of that conduct by a preponderance of the evidence, an individual is liable to the Federal Government for a civil penalty of not more than $50,000 for each violation plus twice the amount of compensation that the individual received or offered for the prohibited conduct, and an organization is liable to the Federal Government for a civil penalty of not more than $500,000 for each violation plus twice the amount of compensation that the organization received or offered for the prohibited conduct. Id. section 2105(b). The adjustments made by this regulation are only applicable to the specific statutory penalty amounts stated in subsections (b)(1) and (b)(2), which are each only one component of the civil penalties imposed under sections 2105(b)(1) and (b)(2).

[7] The Attorney General has authority to bring a civil action when a person has violated or is about to violate a provision under this statute. 42 U.S.C. 5157(b) (2015). The Federal Emergency Management Agency has promulgated regulations regarding this statute and has adjusted the penalty in its regulation. 44 CFR 206.14(d) (2015). The Department of Health and Human Services (HHS) has also promulgated a regulation regarding the penalty under this statute. 42 CFR 38.8 (2015).

[8] Section 1956(b)(1) of Title 18 provides that whoever conducts or attempts to conduct a transaction described in subsection (a)(1) or (a)(3), or section 1957, or a transportation, transmission, or transfer described in subsection (a)(2), is liable to the United States for a civil penalty of not more than the greater of the value of the property, funds, or monetary instruments involved in the transaction; or $10,000. 18 U.S.C. 1956(b)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b)(1)(B), which is only one aspect of the possible civil penalty imposed under section 1956(b).

[9] Section 842(c)(2)(C) of Title 21 provides that in addition to the penalties set forth elsewhere in the subchapter or subchapter II of the chapter, any business that violates paragraph (11) of subsection (a) of the section shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under the section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater. 21 U.S.C. 842(c)(2)(C) (2015). The adjustment made by this regulation regarding the penalty for a succeeding violation is only applicable to the specific statutory penalty amount stated in subsection (c)(2)(C), which is only one aspect of the possible civil penalty for a succeeding violation imposed under section 842(c)(2)(C).

[10] Section 856(d)(1) of Title 21 provides that any person who violates subsection (a) of the section shall be subject to a civil penalty of not more than the greater of $250,000; or 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person. 21 U.S.C. 856(d)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (d)(1)(A), which is only one aspect of the possible civil penalty imposed under section 856(d)(1).

[11] The SUPPORT for Patients and Communities Act, Public Law 115–221 was enacted Oct. 24, 2018.

Dated: May 3, 2022.

Hampton Y. Dellinger,

Assistant Attorney General, Office of Legal Policy.

[FR Doc. 2022–09928 Filed 5–6–22; 8:45 am]

BILLING CODE 4410–19–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0187; FRL–9606–02–R4]

Air Plan Approval; GA; Updates to References to Appendix W Modeling Guidelines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of a State Implementation Plan (SIP) revision submitted by the State of Georgia, through the Georgia Environmental Protection Division (GA EPD) on September 1, 2020. Specifically, EPA is finalizing approval of updates to the incorporation by reference of federal prevention of significant deterioration (PSD) new source review (NSR) regulations in the Georgia SIP. Based on the approval of this SIP revision, EPA is also converting the previous conditional approval regarding Georgia's infrastructure SIP's PSD elements for the 2015 Ozone National Ambient Air Quality Standard (NAAQS) to a full approval. EPA is finalizing approval of these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective June 8, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2022–0187. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Josue Ortiz Borrero, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8085. Mr. Ortiz can also be reached via electronic mail at *ortizborrero.josue@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 1, 2015, EPA promulgated a revised primary and secondary NAAQS for ozone, revising the 8-hour ozone standards from 0.075 parts per million (ppm) to a new more protective level of 0.070 ppm. *See* 80 FR 65292 (October 26, 2015). Pursuant to section 110(a)(1) of the CAA, states are required to submit SIP revisions meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the NAAQS. This particular type of SIP is commonly referred to as an ''infrastructure SIP'' or ''iSIP.'' States were required to submit such SIP revisions for the 2015 8-hour ozone NAAQS to EPA no later than October 1, 2018.[1]

On September 24, 2018, Georgia met its requirement to submit an iSIP for the 2015 8-hour ozone NAAQS by the October 1, 2018, deadline. EPA subsequently approved most of the infrastructure SIP elements for the 2015 Ozone NAAQS for the State. [2] [3] However, regarding the PSD elements of section 110(a)(2)(C), (D)(i)(II) (prong 3), and (J) (hereinafter referred to as element C, Prong 3, and element J, respectively), EPA conditionally approved [4] these portions of Georgia's iSIP submission because of outdated references to the federal guideline on air quality modeling found in Appendix W of 40 CFR part 51.[5]

For elements C and J to be approved for PSD, a state needs to demonstrate that its SIP meets the PSD-related infrastructure requirements of these sections. These requirements are met if the state's implementation plan includes a PSD program that meets current federal requirements. Element D(i)(II) (prong 3) is also approvable when a state's implementation plan contains a fully approved PSD program. EPA's PSD regulations at 40 CFR

[1] In infrastructure SIP submissions, states generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2).

[2] For the State of Georgia, EPA approved most elements, except for the Prong 1 and Prong 2 interstate transport provisions, and the PSD provisions (elements C, Prong 3, and J), on March 11, 2020. *See* 85 FR 14147.

[3] The Prong 1 and Prong 2 interstate transport provisions for Georgia, were approved on 12/2/2021. *See* 86 FR 68413.

[4] Under CAA section 110(k)(4), EPA may conditionally approve a SIP revision based on a commitment from a state to adopt specific enforceable measures by a date certain, but not later than one year from the date of approval. If the state fails to meet the commitment within one year of the final conditional approval, the conditional approval will be treated as a disapproval and EPA will issue a finding of disapproval.

[5] EPA conditionally approved the PSD provisions of element C, Prong 3, and element J on April 15, 2020. *See* 85 FR 20836. The notice of proposed rulemaking associated with the conditional approval provides additional information regarding the CAA's PSD iSIP provisions. *See* 85 FR 7695 (February 11, 2020).

51.166(l) require that modeling be conducted in accordance with Appendix W, *Guideline on Air Quality Models.* EPA promulgated the most current version of Appendix W on January 17, 2017. *See* 82 FR 5182. Therefore, in order to approve the iSIP PSD elements for the 2015 8-hour ozone NAAQS, PSD regulations in SIPs are required to reference the most current version of Appendix W.

As discussed in the conditional approval for the 2015 ozone iSIP PSD elements, Georgia's SIP contained outdated references to Appendix W, and the State committed to update the outdated references and submit a SIP revision within one year of EPA's final rule conditionally approving these PSD elements. Accordingly, Georgia was required to make its submission by April 15, 2021. Georgia met this commitment by submitting a SIP revision to correct the deficiencies on September 1, 2020.

Through a Notice of Proposed Rulemaking (NPRM), published on March 16, 2022, EPA proposed to approve the September 1, 2020, revision to the SIP-approved PSD rule and proposed to convert the conditional approval to a full approval for Georgia, regarding element C, Prong 3, and element J, for the 2015 8-hour ozone NAAQS infrastructure SIP.[6] *See* 87 FR 14817. Comments on the March 16, 2022, NPRM were due on or before April 15, 2022. EPA did not receive any comments on the March 16, 2022, NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Georgia Rule 391–3–1–.02(7), titled ''Prevention of Significant Deterioration of Air Quality,'' state effective July 29, 2020.[7] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[8]

III. Final Action

EPA is finalizing approval of the aforementioned changes to the Georgia Rule 391–3–1–.02(7), *Prevention of Significant Deterioration of Air Quality.* EPA is also converting the conditional approval for element C, Prong 3, and element J, for the 2015 8-hour ozone Infrastructure SIPs to a full approval based on these revisions to the SIP-approved PSD regulations for Georgia.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 they meet the criteria of the CAA. This actions 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 CAA; 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 8, 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) of the CAA.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide,

[6] EPA notes that in the March 16, 2022, NPRM, several references to the Georgia rules incorporated by reference contained typographical errors. References to 391–1–.02(7)(b)(21)(xi) and 391–1–.02(7)(b)9, in the March 16, 2022, NPRM, should have read 391–1–.02(7)(b)21.(xi) and 391–1–.02(7)(b)9. instead. *See* 87 FR 14817, at page 14818. Similarly, in the ''Proposed Action'' section of the March 16, 2022, NPRM, the reference to Georgia rule 391–1–02(7), should have read 391–1– .02(7) instead. *See* 87 FR 14817 at page 14819.

[7] This incorporation by reference excludes the automatic recission clause at 391–3–1–.02(7)(a)(2)(iv), and portions of Rule 391–3–1–.02(7) incorporating by reference 40 CFR 52.21(b)(2)(v), and 40 CFR 52.21(b)(3)(iii)(*c*). *See* 40 CFR 52.570(c).

[8] *See* 62 FR 27968 (May 22, 1997).

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

Dated: April 29, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 L—Georgia

§ 52.569 [Removed and Reserved]

■ 2. Remove and reserve § 52.569;

■ 3. In § 52.570, in paragraph (c), amend the table by revising the entry for ''391–3–1–.02(7);'' and in paragraph (e), amend the table by adding an entry at the end of the table for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED GEORGIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
391–3–1–.02(7)	Prevention of Significant Deterioration of Air Quality (PSD).	7/29/2020	5/9/2022, [Insert citation of publication].	Except for the automatic rescission clause at 391–3–1–.02(7)(a)(2)(iv), which EPA disapproved on March 4, 2016. Except for portions of Rule 391–3–1–.02(7) incorporating by reference 40 CFR 52.21(b)(2)(v), and 40 CFR 52.21(b)(3)(iii)(*c*), because those CFR provisions were indefinitely stayed by the Fugitive Emissions Rule in the March 30, 2011 rulemaking and have not been approved into the Georgia SIP.
*	*	*	*	*

* * * * *

(e) * * *

EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	Georgia	September 1, 2020	5/9/2022, [Insert citation of publication].	Addressing the PSD provisions related to major sources under sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) (prong 3), and 110(a)(2)(J) only.

[FR Doc. 2022–09706 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0062; FRL–9504–02–R4]

Air Plan Approval; NC; Great Smoky Mountains National Park, Raleigh-Durham-Chapel Hill and Rocky Mount Areas Limited Maintenance Plans for the 1997 8-Hour Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve state implementation plan (SIP) revisions submitted by the State of North Carolina, through the North Carolina Department of Environment and Natural Resources, Division of Air Quality (NCDAQ), in a letter dated September 22, 2020. The SIP revisions include the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plans (LMPs) for the Great Smoky Mountains National Park (GSMNP), Raleigh-Durham-Chapel Hill (Triangle) and Rocky Mount, North Carolina Areas (collectively, ''Areas''). EPA is finalizing approval of the LMPs for the Areas because each LMP provides for the maintenance of the 1997 8-hour ozone NAAQS within each of the Areas through the end of the second 10-year portion of the maintenance period. This action makes certain commitments related to maintenance of the 1997 8-hour ozone NAAQS in the Areas federally-enforceable as part of the North Carolina SIP.

DATES: This rule is effective June 8, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0062. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation

Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dianna Myers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9207. Ms. Myers can also be reached via electronic mail at *myers.dianna@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Clean Air Act (CAA or Act), EPA is approving the Areas' LMPs for the 1997 8-hour ozone NAAQS, adopted and submitted by NCDAQ as revisions to the North Carolina SIP on September 22, 2020. On April 15, 2004, EPA published a final rule designating the GSMNP, Triangle and Rocky Mount Areas nonattainment for the 1997 8-hour ozone NAAQS.[1] The GSMNP nonattainment area included portions of Haywood and Swain Counties. The Triangle nonattainment area included Durham, Franklin, Granville, Johnston, Orange, Person and Wake Counties in their entirety and the Townships of Baldwin, Center, New Hope and Williams in Chatham County. The Rocky Mount nonattainment area included Edgecombe and Nash Counties in their entirety. Subsequently, EPA approved the maintenance plans for the GSMNP, Triangle and Rocky Mount Areas and redesignated the Areas to attainment for the 1997 8-hour ozone NAAQS.[2]

The Areas' LMPs for the 1997 8-hour ozone NAAQS, submitted by NCDAQ on September 22, 2020, are designed to maintain the 1997 8-hour ozone NAAQS within the GSMNP, Triangle and Rocky Mount Areas through the end of the second 10-year portion of the maintenance period beyond redesignation. As a general matter, the Areas' LMPs rely on the same control measures and relevant contingency provisions to maintain the 1997 8-hour ozone NAAQS during the second 10-year portion of the maintenance period as the maintenance plan submitted by NCDAQ for the first 10-year period.

In a notice of proposed rulemaking (NPRM), published on February 11, 2022 (87 FR 7970), EPA proposed to approve the Areas' LMPs because the State made a showing, consistent with EPA's prior LMP guidance, that the GSMNP, Triangle and Rocky Mount 1997 8-hour NAAQS Areas' ozone concentrations are well below the 1997 8-hour ozone NAAQS and have been historically stable and that it met the other maintenance plan requirements. The details of North Carolina's submission and the rationale for EPA's action are explained further in the February 11, 2022, NPRM. Comments on the February 11, 2022, NPRM were due on or before March 14, 2022.

II. Response to Comments

One Commenter provided two separate comments on the February 11, 2022, NPRM. EPA's responses to those comments are provided below.

Comment 1: The Commenter indicates that North Carolina's SIP submissions and EPA's proposed approval are reliant on emissions from North Carolina's vehicle inspection and maintenance (I/M) program. Specifically, the Commenter expresses concerns about the effectiveness of the I/M program, citing expired tags, which the Commenter asserts indicate lapsed inspections and taxes to support highway safety measures.

Response 1: Neither of the maintenance plans for GSMNP and Rocky Mount are reliant on emission reductions from North Carolina's I/M program, so the comment is not applicable to this action as it relates to those areas. No county in the GSMNP and Rocky Mount Areas is subject to the North Carolina I/M program, and in a previous action, EPA approved a SIP revision which removed the applicable counties in the GSMNP and Rocky Mount Areas from North Carolina's I/M program on the basis that the emissions reductions from the program in these counties were not necessary to attain or maintain the NAAQS or meet any other applicable requirement of the CAA.[3] *See* 83 FR 48383 (September 25, 2018).

With regards to the Triangle Area, the maintenance plan is partially reliant on emission reductions from North Carolina's I/M program. As mentioned above, the Triangle Area includes Durham, Franklin, Granville, Johnston, Orange, Person and Wake Counties in their entirety and the Townships of Baldwin, Center, New Hope and Williams in Chatham County. Person County was never subject to North Carolina's I/M program, and thus, no emissions reductions from Person County related to North Carolina's I/M program were ever relied on in North Carolina's maintenance plan for the Triangle. Additionally, in the aforementioned September 25, 2018 action, EPA approved a SIP revision removing Chatham, Granville and Orange Counties in the Triangle Area from North Carolina's I/M program, finding that emission reductions from North Carolina's I/M programs were not needed from Chatham (which includes the Townships of Baldwin, Center, New Hope, and Williams), Granville and Orange Counties in the Triangle Area for that Area to stay in attainment and show continued maintenance for the NAAQS. *See* 83 FR 48383. Durham, Franklin, Johnston and Wake Counties are still subject to North Carolina's I/M program, and in a recent action, EPA approved a SIP revision from North Carolina to change the model year coverage for vehicles subject to North Carolina's I/M program. *See* 84 FR 47889 (September 11, 2019). In that action, EPA affirmed that the change to the model year coverage for vehicles in the applicable counites in the Triangle Area would not interfere with NAAQS compliance.

While EPA appreciates the Commenter's concerns related to possible expired tags, this is an enforcement and compliance issue, and expired tags alone are not indicative of the Triangle Area not being in overall compliance with the NAAQS. Ambient air monitoring is the tool that EPA uses to determine ongoing compliance with the NAAQS in this Area. Currently, the Triangle Area is in compliance for all NAAQS, and has been in compliance with all NAAQS for the past several years. EPA also notes that EPA's SIP authority does not extend to requiring taxes to support highway safety measures, so this concern is not relevant to EPA's action.

Comment 2: The Commenter appears to indicate that monitors in Wake County are not sited correctly to measure ambient air quality in the County, and therefore, do not provide adequate data to support EPA's action. Specifically, the Commenter questions the placement of the monitors, the sufficiency of the data that is collected, and the methods used to collect the data. In support of these assertions, the Commenter compares the Town of Fuquay Varina, metropolitan downtown Raleigh, and Durham (''the State Capital''). The Commenter also asserts that projects may have been

[1] *See* 69 FR 23857.

[2] *See* 74 FR 63995 (December 7, 2009), 72 FR 72948 (December 26, 2007), and 71 FR 64891 (November 6, 2006).

[3] Swain County in the GSMNP area was never subject to North Carolina's I/M program.

''intentionally steered clear'' of monitors ''to provide an unrealistic picture of Wake County air degradation.''

Response 2: EPA disagrees with the Commenter's assertion that the monitors in Wake County are not sited appropriately to collect sufficient data to determine compliance with the NAAQS and support EPA's action. By regulation, states are required annually to submit monitoring network plans to provide their strategies for measuring ambient air quality statewide. EPA reviews these air monitoring network plans and makes determinations as to whether the plans are consistent with EPA's monitoring requirements at 40 CFR part 58. EPA last approved North Carolina's monitoring network plan on October 27, 2021, and made the determination (among other determinations) that North Carolina's monitoring network is adequate to measure ambient air quality for ozone statewide, including in Wake County.[4] As discussed in the NPRM, the LMPs for the Areas contain the State's commitment to continue to maintain a monitoring network in accordance with EPA requirements.

Further, EPA is not clear on the Commenter's assertion that projects may have been ''intentionally steered clear'' of monitors ''to provide an unrealistic picture of Wake County air degradation,'' and how this relates to air quality in the County. Notably, ozone is not directly emitted but instead is formed in the atmosphere under certain conditions with a mix of precursors, so it would not be possible for projects to be ''intentionally steered clear'' of ozone monitors to hypothetically manipulate air quality in the Area. In addition, the Commenter does not provide any technical information to support the assertions that ambient air quality monitoring in Wake County is not adequate.

III. Final Action

EPA is taking final action to approve the GSMNP, Triangle and Rocky Mount LMPs for the 1997 8-hour ozone NAAQS, submitted by NCDAQ on September 22, 2020, as revisions to the North Carolina SIP. EPA is approving the Areas' LMPs because each LMP includes an sufficient update of various elements of the 1997 8-hour ozone NAAQS Maintenance Plans approved by EPA for the first 10-year period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions), and retains the relevant provisions of the SIP under sections 110(k) and 175A of the CAA.

EPA also finds that the Areas qualify for the LMP option and that the Areas' LMPs are sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Areas over the second 10-year maintenance period (*i.e.,* through January 6, 2030 for the GSMNP Area, through January 5, 2027, for the Rocky Mount Area, and through December 26, 2027, for the Triangle Area).

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 CAA. These actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For that reason, these actions:

- Are not significant regulatory actions 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);
- Do not impose information collection burdens under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having significant economic impacts on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandates or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are 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 CAA; and
- Do 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).

These SIP revisions are 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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 these actions 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**. These actions are not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of these actions must be filed in the United States Court of Appeals for the appropriate circuit by July 8, 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. These actions may not be challenged later in proceedings to enforce their requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

[4] EPA's approval letter for North Carolina's monitoring network is included in the docket for this final rulemaking.

Dated: April 29, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 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 II—North Carolina

■ 2. In § 52.1770(e), amend the table by adding an entry for ''1997 8-hour Ozone NAAQS 2nd Maintenance Plans (Limited Maintenance Plans) for the Great Smoky Mountains National Park, Raleigh-Durham-Chapel Hill, and Rocky Mount, North Carolina Areas'' at the end of the table to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NORTH CAROLINA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	Federal Register citation	Explanation
* * * * *		*	*	
1997 8-hour Ozone NAAQS 2nd Maintenance Plans (Limited Maintenance Plans) for the Great Smoky Mountains National Park, Raleigh-Durham-Chapel Hill, and Rocky Mount, North Carolina Areas.	9/22/2020	5/9/2022	[Insert citation of publication].	

[FR Doc. 2022–09703 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0686; FRL–9124–02–R4]

Air Plan Approval; Kentucky; Fugitive Emissions Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of a State Implementation Plan (SIP) revision submitted by the Commonwealth of Kentucky (Commonwealth), through the Energy and Environmental Cabinet (Cabinet) on October 15, 2020. The SIP revision updates the Commonwealth's regulation for the control of fugitive emissions. This revision contains minor non-substantive changes, grammatical edits, renumbering, the removal of one provision, the addition of one new requirement, and the incorporation of two definitions to support the new requirement. EPA is finalizing approval of these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective June 8, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0686. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 15, 2020, the Commonwealth submitted changes to the Kentucky SIP for EPA approval.[1] The changes include updates to Regulation 401 KAR 63:010—*Fugitive Emissions,* which establishes control requirements for fugitive emissions. The October 15, 2020, SIP revision contains primarily minor non-substantive changes which concern minor language edits and renumbering changes throughout regulation 401 KAR 63:010. Additionally, the revision includes the removal of one provision regarding nuisances, the addition of one new requirement to use EPA's Reference Method 22, and the incorporation of two new definitions for ''Emission time'' and ''Observation period,'' to support this new requirement.

On March 8, 2022, EPA publish a notice of proposed rulemaking (NPRM) to approve the October 15, 2020, SIP revisions regarding 401 KAR 63:010. EPA's March 8, 2022, NPRM provides additional details regarding the background for this action and EPA's rationale for approving this revision. *See* 87 FR 12904. Comments on the March 8, 2022, NPRM were due on or before April 7, 2022. EPA received no comments on the March 8, 2022, NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Kentucky's Regulation 401 KAR 63:010—*Fugitive Emissions,* state effective on June 30, 2020, which

[1] EPA notes that the Commonwealth's submission was received on October 16, 2020. However, for clarity, EPA will refer to this submission by its cover letter date of October 15, 2020.

updates the Commonwealth's fugitive emission provisions, except for the nuisance provision added to Section 3, Paragraph (4).[2] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

III. Final Action

EPA is approving the revision to Regulation 401 KAR 63:010—*Fugitive Emissions,* which updates the Commonwealth's fugitive emissions rule. EPA is finalizing the approval of these changes to the SIP because they are consistent with the CAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 CAA. 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 CAA; 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 8, 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) of the CAA.

List of Subjects in 40 CFR Part 52

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

Dated: April 29, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 S—Kentucky

■ 2. In § 52.920(c), table 1 is amended by revising the entry for ''401 KAR 63:010'' to read as follows:

§ 52.920 Identification of plan.

* * * * *

(c) * * *

[2] EPA notes that throughout the March 8, 2022, NPRM, the Agency referenced to this provision as paragraph 3(4). EPA's intention was to reference Section 3, Paragraph (4), which was shorthanded to paragraph 3(4).

[3] *See* 62 FR 27968 (May 22, 1997).

TABLE 1—EPA-APPROVED KENTUCKY REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
401 KAR 63:010	Fugitive emissions	6/30/2020	5/9/2022 [Insert citation of publication].	Except for the nuisance provision found in Section 3, Paragraph (4).
*	*	*	*	*

* * * * *

[FR Doc. 2022–09704 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0573; FRL–9453–01–R9]

Air Plan Approval; California; Mojave Desert Air Quality Management District, Placer County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Mojave Desert Air Quality Management District (MDAQMD) and the Placer County Air Pollution Control District (PCAPCD) portions of the California State Implementation Plan (SIP). These revisions concern emissions of volatile organic compounds (VOCs) from metal coating operations and general regulatory definitions. We are also finalizing the rescission of South Coast Air Quality Management District (SCAQMD) Rule 1107, Coating of Metal Parts and Products, as it applies to the Riverside County portion of the MDAQMD. We are approving these revisions, including local rules and a rescission, under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on June 8, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0573. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (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. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3024 or by email at *lazarus.arnold@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On May 20, 2021,[1] the EPA proposed to approve the following rules into the California SIP.

Local agency	Rule No.	Rule title	Amended	Submitted
MDAQMD	1115	Metal Parts & Products Coating Operations	June 8, 2020	July 24, 2020.
PCAPCD	102	Definitions	June 11, 2020	July 24, 2020.

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements.

In addition to replacing the previous versions of the submitted rules listed in Table 1, the EPA proposed to rescind South Coast Air Quality Management District (SCAQMD) Rule 1107, Coating of Metal Parts and Products, as it applies to the Riverside County portion of the MDAQMD, as requested by the California Air Resources Board (CARB).[2]

In our May 20, 2021 proposal, the EPA also proposed to approve revisions to SCAQMD Rule 1107; however, we are not finalizing that action at this time. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. We received three comments during this period, and each one was supportive of this proposed action.

III. EPA Action

No comments were submitted that change our assessment of the rules and rule rescission discussed above and as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving these rules and rule rescission into the California SIP

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In

[1] 86 FR 27344.

[2] CARB's rescission request cites to four Code of Federal Regulations (CFR) provisions for SCAQMD Rule 1107; however, since three of the CFR provisions are previous versions of the Rule that were replaced by more recent versions, and are therefore no longer in the SIP, EPA is interpreting this as a request to remove the latest (and only) version of SCAQMD Rule 1107 applicable in the Riverside County portion of the MDAQMD, namely, the version submitted on May 13, 1993, and listed at 40 CFR 52.220(c)(193)(i)(A)(1).

accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the MDAQMD and the PCAPCD rules described in section I. of this preamble and set forth below in the amendments to 40 CFR part 52. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. 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 Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the 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 the 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).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the 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 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. The 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 July 8, 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 in 40 CFR Part 52

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

Dated: April 29, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations 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 F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(193)(i)(A)(*4*), (c)(419)(i)(B)(*2*), (c)(518)(i)(A)(*6*), and (c)(571) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(193) * * *

(i) * * *

(A) * * *

(*4*) Previously approved on February 1, 1984 in paragraph (c)(193)(i)(A)(1) of this section and now deleted without replacement for implementation in the Mojave Desert Air Quality Management District (Riverside County), Rule 1107.

* * * * *

(419) * * *

(i) * * *

(B) * * *

(*2*) Previously approved on January 31, 2013 in paragraph (c)(419)(i)(B)(1) of this section and now deleted with replacement in (c)(571)(i)(B)(1), Rule 102, ''Definitions,'' amended February 9, 2012.

* * * * *

(518) * * *

(i) * * *

(A) * * *

(*6*) Previously approved on February 27, 2020 in paragraph (c)(518)(i)(A)(2) of this section and now deleted with replacement in (c)(571)(i)(A)(1), Rule 1115, ''Metal Parts and Products Coating Operations,'' amended on January 22, 2018.

* * * * *

(571) Amended regulations for the following APCDs were submitted on July 24, 2020 by the Governor's designee as an attachment to a letter dated July 23, 2020.

(i) Incorporation by reference.

(A) Mojave Desert Air Quality Management District.

(*1*) Rule 1115, ''Metal Parts and Products Coating Operations,'' amended on June 8, 2020.

(*2*) [Reserved]

(B) Placer County Air Pollution Control District.

(*1*) Rule 102, ''Definitions,'' amended on June 11, 2020.

(*2*) [Reserved]

(ii) [Reserved]

[FR Doc. 2022–09726 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0445; FRL–9621–02–R4]

Air Plan Approval; SC; 2018 General Assembly Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of a State Implementation Plan (SIP) revision submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SC DHEC or Department), on April 24, 2020. The SIP revision updates the numbering and formatting of South Carolina's regulations applicable to emissions inventories, emissions statements, and credible evidence. EPA is finalizing approval of these changes pursuant to the Clean Air Act (CAA or Act) and implementing Federal regulations.

DATES: This rule is effective June 8, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2020–0445. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 24, 2020, SC DHEC submitted a SIP revision to EPA for approval that includes changes to South Carolina Regulation 61–62.1, *Definitions and General Requirements.* In this document, EPA is finalizing approval to incorporate into South Carolina's SIP updates to Section III—*Emissions Inventory and Emissions Statements* and Section V—*Credible Evidence* of South Carolina Regulation 61–62.1.[1] EPA is finalizing approval of these changes because they meet the requirements of and are consistent with the CAA.

In a notice of proposed rulemaking (NPRM) published in the *Federal Registe*r on March 8, 2022 (87 FR 12902), EPA proposed to approve the aforementioned changes from South Carolina's April 24, 2020, SIP revision. The details of South Carolina's submittal and the rationale for EPA's approval are further explained in the March 8, 2022, NPRM. Comments on the March 8, 2022, NPRM were due on or before April 7, 2022. EPA did not receive any comments, adverse or otherwise, on the March 8, 2022, NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of South Carolina's Regulation 61–62.1, *Definitions and General Requirements,* Section III—*Emissions Inventory and Emissions Statements* and Section V—*Credible Evidence,* state effective on April 24, 2020. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[2]

III. Final Action

EPA is finalizing approval of revisions to the SIP-approved version of South Carolina's Regulation 61–62.1, Section III—*Emissions Inventory and Emissions Statements* and Section V—*Credible Evidence,* state effective on April 24, 2020. EPA has determined that these revisions meet the applicable requirements of section 110 of the CAA and the applicable regulatory requirements at 40 CFR part 51.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 CAA. 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);

[1] The April 24, 2020, submittal from SC DHEC includes other updates and revisions as well. EPA previously acted on Section I—*Definitions* of South Carolina Regulation 61–62.1. *See* 86 FR 59641 (October 28, 2021). EPA has not taken action on Section II—*Permit Requirements* and Section IV—*Source Tests* of South Carolina Regulation 61–62.1. EPA will address these other provisions in separate actions.

[2] *See* 62 FR 27968 (May 22, 1997).

• 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 CAA; 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).

Because this final rule merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law, this final rule for the State of South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, this action will not impose substantial direct costs on Tribal governments or preempt Tribal law. The Catawba Indian Nation (CIN) Reservation is located within the boundary of York County, South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120 (Settlement Act), ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' The CIN also retains authority to impose regulations applying higher environmental standards to the Reservation than those imposed by state law or local governing bodies, in accordance with the Settlement Act.

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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 8, 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) of the CAA.

List of Subjects in 40 CFR Part 52

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

Dated: April 29, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 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 PP—South Carolina

■ 2. In § 52.2120(c), amend the table, under the heading for ''Regulation No. 62.1,'' by revising the entries for ''Section III'' and ''Section V'' to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(c) * * *

EPA-Approved South Carolina Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
Regulation No. 62.1	Definitions and General Requirements.			
*	* * *	*	*	* *
Section III	Emissions Inventory and Emissions Statements.	4/24/2020	5/9/2022, [Insert citation of publication].	
*	* * *	*	*	* *
Section V	Credible Evidence	4/24/2020	5/9/2022, [Insert citation of publication].	
*	* * *	*	*	* *

* * * * *

[FR Doc. 2022–09705 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 214

Railroad Workplace Safety

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

In Title 49 of the Code of Federal Regulations, parts 200 to 299, revised as of October 1, 2021, make the following corrections:

■ 1. Amend § 214.115 by revising paragraph (b) to read as follows:

§ 214.115 Foot protection.

* * * * *

(b) Foot protection equipment required by this section shall conform to the requirements of 29 CFR 1910.136(b), as established by the U.S. Department of Labor, Occupational Safety and Health Administration.

■ 2. Amend § 214.117 by revising paragraph (b) to read as follows:

§ 214.117 Eye and face protection.

* * * * *

(b) Eye and face protection equipment required by this section shall conform to the requirements of 29 CFR 1910.133(b), as established by the U.S. Department of Labor, Occupational Safety and Health Administration.

* * * * *

[FR Doc. 2022–09991 Filed 5–6–22; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 201204–0325]

RIN 0648–BL44

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2021–2022 Biennial Specifications and Management Measures; Inseason Adjustments

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

ACTION: Final rule; inseason adjustments to biennial groundfish management measures.

SUMMARY: This final rule announces routine inseason adjustments to the harvest limits for incidental Pacific halibut retention in the sablefish primary fishery. This action decreases the incidental Pacific halibut catch limit to ensure equitable harvest opportunities without exceeding the harvest limit.

DATES: This final rule is effective May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Keeley Kent, phone: (206) 526–4655) or email: *keeley.kent@noaa.gov*.

Electronic Access

This rule is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov*. Background information and documents are available at the Pacific Fishery Management Council's website at *http://www.pcouncil.org/*.

SUPPLEMENTARY INFORMATION:

Background

The Pacific Coast Groundfish Fishery Management Plan (PCGFMP), and its implementing regulations at title 50 in the Code of Federal Regulations (CFR), 660, subparts C through G, regulate fishing for over 90 species of groundfish off the coasts of Washington, Oregon, and California. The Pacific Fishery Management Council (Council) develops groundfish harvest specifications and management measures for two-year periods (*i.e.,* a biennium). NMFS published the final rule to implement harvest specifications and management measures for the 2021–2022 biennium for most species managed under the PCGFMP on December 11, 2020, (85 FR 79880). NMFS also published a correction (85 FR 86853, December 31, 2020), and a correcting amendment (86 FR 14379, March 16, 2021) to implement the Council's recommendations for the 2021–2022 harvest specifications and management measures.

In general, the management measures set at the start of the biennial harvest specifications cycle help the various sectors of the fishery attain, but not exceed, the catch limits for each stock. The Council, in coordination with Pacific Coast Treaty Indian Tribes and the states of Washington, Oregon, and California, recommends adjustments to the management measures during the fishing year to achieve this goal.

At its March 8–14, 2022 meeting, the Council recommended decreasing the amount of Pacific halibut that vessels in the sablefish primary fishery north of Point Chehalis, WA, may retain incidentally to ensure that catch of Pacific halibut stays within its annual allocation. Pacific Coast groundfish fisheries are managed using harvest specifications or limits (*e.g.,* overfishing limits [OFL], acceptable biological catch [ABC], annual catch limits [ACL] and harvest guidelines [HG]) recommended biennially by the Council and based on the best scientific information available at that time (50 CFR 660.60(b)). During development of the harvest specifications, the Council also recommends management measures (*e.g.,* trip limits, area closures, and bag limits) that are meant to mitigate catch so as not to exceed the harvest specifications. The harvest specifications and mitigation measures developed for the 2021–2022 biennium used data through the 2019 fishing year. Each of the adjustments to management measures discussed below are based on updated fisheries information that was unavailable when the analysis for the current harvest specifications was completed. As new fisheries data becomes available, adjustments to management measures are projected so as to help harvesters achieve but not exceed the harvest limits.

Pacific halibut is generally a prohibited species for vessels fishing in Pacific Coast groundfish fisheries, unless explicitly allowed in groundfish regulations. The Council developed a Catch Sharing Plan for the International Pacific Halibut Commission (IPHC) Regulatory Area 2A, as provided for in the Northern Pacific Halibut Act of 1982 (16 U.S.C. 773–773k) (Halibut Act), to allocate the Area 2A annual catch limit for Pacific halibut among fisheries off Washington, Oregon, and California. The IPHC annually sets allocations for the various IPHC regulatory areas, including Area 2A and NMFS implements these allocations for fishing in U.S. waters pursuant to the Halibut Act. NMFS also annual implements management measures and approves changes to the Catch Sharing Plan for Area 2A.

Under the Catch Sharing Plan, the sablefish primary fishery north of Point Chehalis, WA (46°53.30′ N. lat.) is allocated a portion of the Washington recreational allocation, which varies via a catch limit-dependent formula, as described in the Catch Sharing Plan and in regulations at 50 CFR 300.63(b)(3).

The sablefish primary fishery season is open from April 1 to October 31, though the fishery may close for

individual participants prior to October 31 once they reach the cumulative limit associated with their tier assignment(s) for the primary fishery. Regulations at § 660.231(b)(3)(iv) allow vessels fishing in the sablefish primary fishery with a permit from the IPHC to retain Pacific halibut up to a set landing limit, which may be reviewed and modified throughout the sablefish primary fishery season to allow for attainment, but not exceedance of the Pacific halibut allocation. The objectives for the annual landing restrictions are to allow for incidental Pacific halibut catch and attain the Pacific halibut allocation, at about the same time the sablefish primary season ends (October 31), and to ensure an equitable sharing of the Pacific halibut landings among fishers.

On March 7, 2022, NMFS implemented a 2022 Area 2A catch limit of 1,490,000 pounds (lb) (675.9 metric tons (mt)) (87 FR 12604). As specified by the Catch Sharing Plan, since the 2022 Area 2A catch limit is less than 1.5 million pounds (680.4 mt), the incidental halibut limit for the sablefish primary fishery's allocation is 50,000 lb (22.7 mt) (87 FR 12604, March 7, 2022). In 2021, due to economic uncertainty, harvest during the regular sablefish primary fishery season was lower than predicted. As a result, at the September 2021 Council meeting, the Council recommended, and NMFS implemented, an emergency rule to extend the sablefish primary season, normally scheduled to end on October 31, until December 31, 2021 (86 FR 59873, October 29, 2021). Also, as part of that emergency rule, the incidental Pacific halibut retention allowance continued until the close of the Pacific halibut season on December 7, 2021. The 2021 season concluded with 98.7 percent of the 70,000 lb (31.8 mt) allowance for Pacific halibut landed. The effects of economic uncertainty resulting from the COVID–19 pandemic on sablefish primary fishery harvest are expected to be lessened in 2022, compared to 2021. If fishing patterns return to more typical seasonal efforts in 2022, the incidental Pacific halibut retention limit in place in 2021 may be too high, and harvest of Pacific halibut may accrue too quickly to allow retention throughout the entire sablefish primary season, which is ends on October 31, 2022. In addition, the incidental limit for Pacific halibut is 20,000 lb less than in 2021, at 50,000 lb. The most recent year with a 50,000 lb limit was 2018, and in that year 87 percent of the allocation was harvested. From 2019–2021, the 70,000 lb limit was between 90 and 113 percent attained each year. Therefore, at the March 2022 virtual meeting, the Council recommended a reduction in Pacific halibut retention allowance early in the 2022 sablefish primary fishery season to discourage targeted fishing while allowing small incidental catches through the end of the season on October 31.

The Council recommended, and NMFS is revising the incidental Pacific halibut retention regulations at § 660.231(b)(3)(iv) to decrease the incidental Pacific halibut catch limit to enable some incidental catch without exceeding the harvest limit. The limit will be reduced from 225 lb (102 kg) dressed weight of halibut for every 1,000 lb (454 kg) dressed weight of sablefish landed, and up to two halibut in excess of the ratio, to 150 lb (68 kg) dressed weight of halibut for every 1,000 lb (454 kg) dressed weight of sablefish landed, and up to two halibut in excess of the ratio. This decrease is expected to allow opportunity for total catch of Pacific halibut to attain, but not exceed, the 2022 allocation for the sablefish primary fishery north of Point Chehalis, WA (50,000 lb or 22.7 mt).

Classification

This final rule makes routine inseason adjustments to groundfish fishery management measures, based on the best scientific information available, consistent with the PCGFMP and its implementing regulations.

This action is taken under the authority of 50 CFR 660.60(c) and is exempt from review under Executive Order 12866.

The aggregate data upon which these actions are based are available for public inspection by contacting Keeley Kent in NMFS' West Coast Region (see **FOR FURTHER INFORMATION CONTACT**, above), or view at the NMFS West Coast Groundfish website: *https://www.fisheries.noaa.gov/species/west-coast-groundfish*.

Pursuant to 5 U.S.C. 553(b), NMFS finds good cause to waive prior public notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. The adjustments to management measures in this document affect commercial fisheries off the coast of Washington. No aspect of this action is controversial, and changes of this nature were anticipated in the final rule for the 2021–2022 harvest specifications and management measures, which was published on December 11, 2020 (85 FR 79880). Accordingly, for the reasons stated below, NMFS finds good cause to waive prior notice and comment.

At its March 2022 meeting, the Council recommended the decrease to the incidental Pacific halibut retention limit for vessels fishing in the sablefish primary fishery north of Point Chehalis. The sablefish primary fishery opened on April 1. The Council recommends this precautionary reduction be implemented as soon as possible, early in the season, in an effort to prolong the amount of time Pacific halibut may be retained in the sablefish primary fishery north of Point Chehalis.

Delaying implementation to allow for public comment would make it more likely for the sablefish primary fishery north of Point Chehalis to exceed its 2022 allocation of Pacific halibut before the end of the sablefish primary fishery season. Therefore, providing a comment period for this action could limit the equitable benefits to the fishery, and the vessels that participate in the fishery, as they rely on the Pacific halibut retention allowance throughout the entire season and could result in a greater risk of exceeding the Pacific halibut harvest allocation.

Because prior notice and an opportunity for public comment are not required to be provided for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no Regulatory Flexibility Analysis is required for this rule and none has been prepared.

Therefore, the NMFS finds reason to waive the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d)(1) so that this final rule may become effective upon publication in the **Federal Register**. The adjustments to management measures in this document affect commercial fisheries by decreasing the incidental halibut retention limit in the sablefish primary fishery north of Point Chehalis, WA. This adjustment was requested by the Council's advisory bodies, as well as members of industry during the Council's March 2022 meeting, and recommended unanimously by the Council. No aspect of this action is controversial, and changes of this nature were anticipated in the biennial harvest specifications and management measures established through a notice and comment rulemaking for 2021–2022 (85 FR 79880, December 11, 2020).

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian Fisheries.

Dated: May 4, 2022.

Jennifer M. Wallace,

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

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.231, revise paragraph (b)(3)(iv) to read as follows:

§ 660.231 Limited entry fixed gear sablefish primary fishery.

* * * * *

(b) * * *

(3) * * *

(iv) Incidental Pacific halibut retention north of Pt. Chehalis, WA (46°53.30′ N lat.). From April 1 through October 31, vessels authorized to participate in the sablefish primary fishery, licensed by the International Pacific Halibut Commission for commercial fishing in Area 2A (waters off Washington, Oregon, California), and fishing with longline gear north of Pt. Chehalis, WA (46°53.30′ N lat.) may possess and land up to 150 lbs (68 kg) dressed weight of Pacific halibut for every 1,000 lbs (454 kg) dressed weight of sablefish landed, and up to two additional Pacific halibut in excess of the 150-lbs-per-1,000-pound limit per landing. ''Dressed'' Pacific halibut in this area means halibut landed eviscerated with their heads on. Pacific halibut taken and retained in the sablefish primary fishery north of Pt. Chehalis may only be landed north of Pt. Chehalis and may not be possessed or landed south of Pt. Chehalis.

* * * * *

[FR Doc. 2022–09902 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 89
Monday, May 9, 2022

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0513; Project Identifier MCAI–2021–01162–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

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 Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports that the thrust reverser correction factors presented in certain airplane flight manual (AFM) performance charts for landing on contaminated runways do not provide sufficient margin for stopping distances in certain conditions. This proposed AD would require revising the existing AFM to correct the affected performance charts. 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 June 23, 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 Bombardier, Inc., Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com*; internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0513; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@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–2022–0513; Project Identifier MCAI–2021–01162–T'' 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 the 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 Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@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

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2021–35, dated October 26, 2021 (TCCA AD CF–2021–35) (also referred to after this as the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0513.

This proposed AD was prompted by reports that the thrust reverser correction factors presented in certain AFM performance charts for landing on contaminated runways do not provide sufficient margin for stopping distances in certain conditions. The FAA is proposing this AD to address incorrect AFM performance charts, which if not corrected, could lead to longitudinal runway excursions. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued the following service information, which specifies revised AFM limitations and corrections to the performance charts for landing on contaminated runways. These documents are distinct since they apply to different airplane models and configurations.

The following paragraphs and supplements of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1, Revision 109, dated August 16, 2021. (For obtaining this section of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1, use Document Identification No. GL 700 AFM–1.)

- Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2., Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.
- Paragraph A., Improved Climb Performance, of Section 6—Performance, of Supplement 5—Improved Climb Performance, of Chapter 7—Supplements.
- Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

The following paragraphs and supplements of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1A, Revision 109, dated August 16, 2021. (For obtaining this section of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1A, use Document Identification No. GL 700 AFM–1A.)

- Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.
- Paragraph A., Improved Climb Performance, of Section 6—Performance, of Supplement 5—Improved Climb Performance, of Chapter 7—Supplements.
- Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

The following paragraphs and supplements of the Bombardier Global 6000 Airplane Flight Manual—Publication No. CSP 700–1V, Revision 39, dated August 16, 2021. (For obtaining this section of the Bombardier Global 6000 Airplane Flight Manual—Publication No. CSP 700–1V, use Document Identification No. GL 6000 AFM.)

- Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2., Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.
- Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph A., Take-off on Wet Grooved Runways, of Section 6—Performance, of Supplement 35—Operation on Wet Grooved Runways, of Chapter 7—Supplements.

The following paragraphs and supplements of the Bombardier Global 5000 Airplane Flight Manual—Publication No. CSP 700–5000–1, Revision 70, dated August 16, 2021. (For obtaining this section of the Bombardier Global 5000 Airplane Flight Manual—Publication No. CSP 700–5000–1, use Document Identification No. GL 5000 AFM.)

- Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.
- Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

The following paragraphs and supplements of the Bombardier Global 5000 Featuring Global Vision Flight Deck (GVFD) Airplane Flight Manual—Publication No. CSP 700–5000–1V,

Revision 39, dated August 16, 2021. (For obtaining this section of the Bombardier Global 5000 Featuring Global Vision Flight Deck Airplane Flight Manual—Publication No. CSP 700–5000–1V, use Document Identification No. GL 5000 GVFD AFM.)

- Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.
- Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.
- Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.
- Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.
- Paragraph A., Take-off on Wet Grooved Runways, of Section 6—Performance, of Supplement 35—Operation on Wet Grooved Runways, of Chapter 7—Supplements.

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.

FAA's Determination

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 the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

TCCA AD CF–2021–35 requires operators to ''advise all flight crews'' of revisions to the AFM, and thereafter to ''operate the aeroplane accordingly.'' However, this proposed AD would not specifically require those actions as those actions are already required by FAA regulations. FAA regulations require operators furnish to pilots any changes to the AFM (for example, 14 CFR 121.137), and to ensure the pilots are familiar with the AFM (for example, 14 CFR 91.505). As with any other flightcrew training requirement, training on the updated AFM content is tracked by the operators and recorded in each pilot's training record, which is available for the FAA to review. FAA regulations also require pilots to follow the procedures in the existing AFM including all updates. 14 CFR 91.9 requires that any person operating a civil aircraft must comply with the operating limitations specified in the AFM. Therefore, including a requirement in this proposed AD to operate the airplane according to the revised AFM would be redundant and unnecessary.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 408 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$34,680

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:

Bombardier, Inc.: Docket No. FAA–2022–0513; Project Identifier MCAI–2021–01162–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9001 through 9860 inclusive, 9862 through 9871 inclusive, 9873 through 9879 inclusive, 60005, 60024, 60030, 60032, 60037, 60043, 60045, and 60049.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by reports that the thrust reverser correction factors presented in certain airplane flight manual (AFM) performance charts for landing on contaminated runways do not provide sufficient margin for stopping distances in certain conditions. The FAA is issuing this AD to address incorrect AFM performance charts, which if not corrected, could lead to longitudinal runway excursions.

(f) Compliance

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

(g) AFM Revision

Within 30 days after the effective date of this AD: Do the applicable actions specified in paragraph (g)(1) through (5) of this AD.

(1) For Model BD–700–1A10 airplanes with a Global Express marketing designation: Revise the existing AFM to incorporate the information specified in paragraphs (g)(1)(i) through (viii) of this AD. These paragraphs and supplements are of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1, Revision 109, dated August 16, 2021.

Note 1 to paragraph (g)(1): For obtaining this section of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1, use Document Identification No. GL 700 AFM–1.

(i) Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.

(ii) Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.

(iii) Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(iv) Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2., Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(v) Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.

(vi) Paragraph A., Improved Climb Performance, of Section 6—Performance, of Supplement 5—Improved Climb Performance, of Chapter 7—Supplements.

(vii) Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(viii) Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(2) For Model BD–700–1A10 airplanes with a Global Express XRS marketing designation: Revise the existing AFM to incorporate the information specified in paragraphs (g)(2)(i) through (viii) of this AD. These paragraphs and supplements are of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1A, Revision 109, dated August 16, 2021.

Note 2 to paragraph (g)(2): For obtaining this section of the Bombardier Global Express Airplane Flight Manual—Publication No. CSP 700–1A, use Document Identification No. GL 700 AFM–1A.

(i) Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.

(ii) Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.

(iii) Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(iv) Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2., Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(v) Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.

(vi) Paragraph A., Improved Climb Performance, of Section 6—Performance, of Supplement 5—Improved Climb Performance, of Chapter 7—Supplements.

(vii) Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(viii) Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(3) For Model BD–700–1A10 airplanes with a Global 6000 marketing designation: Revise the existing AFM to incorporate the information specified in paragraphs (g)(3)(i) through (viii) of this AD. These paragraphs and supplements are of the Bombardier Global 6000 Airplane Flight Manual—Publication No. CSP 700–1V, Revision 39, dated August 16, 2021.

Note 3 to paragraph (g)(3): For obtaining this section of the Bombardier Global 6000 Airplane Flight Manual—Publication No. CSP 700–1V, use Document Identification No. GL 6000 AFM.

(i) Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.

(ii) Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.

(iii) Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(iv) Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2., Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(v) Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.

(vi) Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(vii) Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(viii) Paragraph A., Take-off on Wet Grooved Runways, of Section 6—Performance, of Supplement 35—Operation on Wet Grooved Runways, of Chapter 7—Supplements.

(4) For Model BD–700–1A11 airplanes with a Global 5000 marketing designation: Revise the existing AFM to incorporate the information specified in paragraphs (g)(4)(i) through (vii) of this AD. These paragraphs and supplements are of the Bombardier Global 5000 Airplane Flight Manual—Publication No. CSP 700–5000–1, Revision 70, dated August 16, 2021.

Note 4 to paragraph (g)(4): For obtaining this section of the Bombardier Global 5000 Airplane Flight Manual—Publication No. CSP 700–5000–1, use Document Identification No. GL 5000 AFM.

(i) Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.

(ii) Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.

(iii) Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing

Condition section of Chapter 6—Performance.

(iv) Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(v) Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.

(vi) Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(vii) Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(5) For Model BD–700–1A11 airplanes with a Global 5000 featuring Global Vision Flight Deck (GVFD) marketing designation: Revise the existing AFM to incorporate the information specified in paragraphs (g)(5)(i) through (viii) of this AD These paragraphs and supplements are of the Bombardier Global 5000 Featuring Global Vision Flight Deck Airplane Flight Manual—Publication No. CSP 700–5000–1V, Revision 39, dated August 16, 2021.

Note 5 to paragraph (g)(5): For obtaining this section of the Bombardier Global 5000 Featuring Global Vision Flight Deck Airplane Flight Manual—Publication No. CSP 700–5000–1V, use Document Identification No. GL 5000 GVFD AFM.

(i) Paragraph C., Wet Runway Take-Off Field Length, of Section 2. Take-Off Performance—Slat Out/Flap 6°, of the Take-Off Performance section of Chapter 6—Performance.

(ii) Paragraph C., Wet Runway Take-Off Field Length, of Section 3. Take-Off Performance—Slat Out/Flap 16°, of the Take-Off Performance section of Chapter 6—Performance.

(iii) Paragraph B., Effects of Cowl Anti-Ice On, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(iv) Paragraph C., Effects of Wing and Cowl Anti-Ice On/Ice Accumulation, of Section 2. Performance Corrections, of the Performance Data for Operation in Icing Condition section of Chapter 6—Performance.

(v) Supplement 3—Operation on Contaminated Runways, of Chapter 7—Supplements.

(vi) Paragraph B., Take-Off Field Length, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(vii) Paragraph G., Operation in Icing Conditions, of Section 6—Performance, of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, of Chapter 7—Supplements.

(viii) Paragraph A., Take-off on Wet Grooved Runways, of Section 6—Performance, of Supplement 35—Operation on Wet Grooved Runways, of Chapter 7—Supplements.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2021–35, dated October 26, 2021, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0513.

(2) For more information about this AD, contact Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier, Inc., Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com*; internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on April 30, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09680 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0474; Airspace Docket No. 22–ACE–11]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Independence, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Independence, IA. The FAA is proposing this action as the result of an airspace review as part of the decommissioning of the Wapsie non-directional beacon (NDB). The name and geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before June 23, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0474/Airspace Docket No. 22–ACE–11 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at James H. Connell Field at Independence Municipal Airport, Independence, IA, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0474/Airspace Docket No. 22–ACE–11.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface within a 6.5-mile (increased from a 6.4-mile) radius of James H. Connell Field at Independence Municipal Airport, Independence, IA; removing the Wapsie NDB and associated extension from the airspace legal description; and updating the name (previously Independence Municipal Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review as part of the decommissioning of the Wapsie NDB which provided navigation information for the instrument procedures this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE IA E5 Independence, IA [Amended]

James H. Connell Field at Independence Municipal Airport, IA
(Lat. 42°27′25″ N, long. 91°56′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of James H. Connell Field at Independence Municipal Airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09682 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0473; Airspace Docket No. 22–ASW–9]

RIN 2120–AA66

Proposed Revocation of Class E Airspace; Rocksprings Four Square Ranch Airport and Sonora Canyon Ranch, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Class E airspace at Rocksprings Four Square Ranch Airport, TX, and Sonora Canyon Ranch, TX. The FAA is proposing this action due to the cancellation of the instrument procedures at the associated airports, and the airspace no longer being required.

DATES: Comments must be received on or before June 23, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0473/Airspace Docket No. 22–ASW–9, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would remove the Class E airspace extending upward from 700 feet above the surface at Four Square Ranch, Rocksprings, TX, and Canyon Ranch Airport, Sonora, TX, due to the cancellation of the instrument procedures at these airports, and the airspace no longer being required.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0473/Airspace Docket No. 22–ASW–9.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Removing the Class E airspace extending upward from 700 feet above the surface at Four Square Ranch Airport, Rocksprings, TX;

And removing the Class E airspace extending upward from 700 feet above the surface at Canyon Ranch Airport, Sonora, TX.

This action is the result of the instrument procedures at these airports being cancelled, and the airspace no longer being required.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Rocksprings Four Square Ranch Airport, TX [Remove]

* * * * *

ASW TX E5 Sonora Canyon Ranch, TX [Remove]

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09679 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R10–OAR–2022–0125; FRL–9489–01–R10]

Air Plan Approval; OR; Oakridge PM_{10} Redesignation to Attainment and Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to redesignate the Oakridge, Oregon nonattainment area (Oakridge NAA or Oakridge area) to attainment for the 1987 National Ambient Air Quality Standard for particulate matter of 10 microns or less (PM_{10} NAAQS). EPA also proposes to approve the Oakridge PM_{10} maintenance plan for the area demonstrating continued compliance with the PM_{10} NAAQS through with the Lane Regional Clean Air Agency (LRAPA), submitted to EPA on January 13, 2022, along with the redesignation request for inclusion into the Oregon State Implementation Plan (SIP). EPA also proposes to approve revisions to LRAPA's rules to reflect the redesignation. Additionally, EPA proposes to approve the PM_{10} motor vehicle emissions budgets included in the maintenance plan and inform the public that we are starting the adequacy process for the proposed motor vehicle emissions budgets, including a public comment period. Finally, EPA proposes to take final agency action on the wildfire exceptional event request submitted by ODEQ on July 22, 2021 and concurred on by EPA on April 1, 2022. EPA proposes these actions pursuant to the Clean Air Act (CAA or the Act).

DATES: Comments must be received on or before June 8, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2022–0125, at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Christi Duboiski (15–H13), EPA Region 10, 1200 Sixth Avenue (Suite 155), Seattle WA, 98101, at (360) 753–9081, or *duboiski.christi@epa.gov*.

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

Table of Contents

I. Background

EPA revised the NAAQS for particulate matter on July 1, 1987, replacing standards for total suspended particulates, particulate less than 30 microns in diameter, with new standards applying only to PM_{10} (52 FR 24634). In 1987, EPA established two PM_{10} standards, an annual standard and a 24-hour standard. In 2006, the 24-hour PM_{10} standards were retained but the annual standards were revoked, effective December 18, 2006 (71 FR 61144, October 17, 2006). On January 15, 2013 and December 18, 2020, EPA announced that it was again retaining the PM_{10} NAAQS as a 24-hour standard of 150 micrograms per cubic meter ($\mu g/m^3$) (78 FR 3086 and 85 FR 82684). An area attains the 24-hour PM_{10} standard when the expected number of days per calendar year with a 24-hour concentration exceeding the standard (referred to as an exceedance), is equal to or less than one. Oregon's January 13, 2022, submittal of the Oakridge PM_{10} maintenance plan addresses the 1987 24-hour PM_{10} standard, as originally promulgated, and as reaffirmed on December 18, 2020.

On December 21, 1993, EPA designated the Oakridge, Oregon urban growth boundary as nonattainment for PM_{10} and classified it as moderate under section 107(d)(3) of the CAA (58 FR 67334). The nonattainment area designation and classification became effective on January 20, 1994, with an attainment date for the area of December 31, 2000.

The nonattainment designation of the Oakridge NAA required Oregon to prepare and submit an attainment plan to meet statutory and regulatory requirements. On December 9, 1996, ODEQ submitted an attainment plan (1996 attainment plan) to EPA, and on March 15, 1999, EPA approved the attainment plan (64 FR 12751). The 1996 attainment plan consisted of an attainment year emission inventory, control measures that meet reasonably available control measures/technology (RACM/RACT), attainment demonstration, motor vehicle emission budgets (MVEBs), demonstration of reasonable further progress (RFP), quantitative milestones and contingency measures. In addition, on July 26, 2001, EPA finalized a determination that the Oakridge NAA attained the PM_{10} NAAQS (Determination of Attainment) by the December 31, 2000, attainment date (66 FR 38947).

II. Clean Air Act Requirements for Redesignation to Attainment

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation provided that: (1) EPA determines that the area has attained the applicable NAAQS; (2) EPA has fully approved the applicable implementation plan for the area under section 110(k) of the CAA; (3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant control regulations and other permanent and enforceable reductions; (4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the state has met all requirements applicable to the area under section 110 and part D of the CAA. In this proposed action, EPA will review CAA section 107(d)(3)(E) requirements (2) and (5) together as part of our evaluation of Oregon's redesignation request.

EPA has provided guidance on redesignation in the ''General Preamble,'' [1] and has provided further guidance on processing redesignation requests in the following documents: (1) ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter the ''Calcagni Memo''); (2) ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and (3) ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994. These documents are included in the Docket for this proposed action.

III. EPA's Analysis of Oregon's Submittal

EPA proposes to redesignate the Oakridge NAA to attainment for the 1987 24-hour PM_{10} NAAQS and proposes to approve into the Oregon SIP the associated Oakridge PM_{10} maintenance plan. EPA's proposed approval of the redesignation request and maintenance plan is based upon EPA's determination that the area continues to attain the 1987 24-hour PM_{10} NAAQS and that all other redesignation criteria have been met for the area. Sections III.A through D of this document describe how Oregon's January 13, 2022, submittal satisfies the requirements of section 107(d)(3)(E) of the CAA for the 1987 24-hour PM_{10} standard. In addition, EPA proposes to approve revisions to LRAPA's rules to reflect the redesignation of the Oakridge PM_{10} and fine particulate matter ($PM_{2.5}$) nonattainment areas.[2]

Oregon's submittal also addresses transportation conformity, MVEBs and emissions from wildfire-influenced PM_{10} concentrations recorded in the Oakridge NAA in 2020. EPA proposes to approve the MVEBs and proposes to approve the exclusion of data associated with the wildfire exceptional events that affected data in September of 2020 for purposes of showing continued attainment of the PM_{10} NAAQS.

A. Attainment Determination

To redesignate an area from nonattainment to attainment, the CAA requires EPA to determine that the area has attained the applicable NAAQS (CAA section 107(d)(3)(E)(i)). An area has attained the 1987 24-hour PM_{10} NAAQS if the average number of expected exceedances per year is less than or equal to one, when averaged over a three-year period.[3] A state must demonstrate that an area has attained the PM_{10} NAAQS through submittal of ambient air quality data from an ambient air monitoring network for PM_{10} to EPA's Air Quality System (AQS) (40 CFR 58.15 and 58.16(a)). Three years of representative data should be used (40 CFR part 50, Appendix K, 2.3(b)).

The Exceptional Events Rule

Congress has recognized that it may not be appropriate for EPA to use certain monitoring data collected by the ambient air quality monitoring network and maintained in EPA's AQS database [4] in certain regulatory determinations. Thus, in 2005, Congress provided the statutory authority for the exclusion of data influenced by

[1] *See* ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498, April 16, 1992.

[2] We note that the January 13, 2022 submittal also includes the Oakridge $PM_{2.5}$ redesignation and maintenance plan and revisions to the Lane County Code, which EPA will address in a separate action.

[3] *See* 40 CFR part 50 and 40 CFR part 50, appendix K.

[4] AQS is EPA's official repository of ambient air data.

''exceptional events'' meeting specific criteria by adding section 319(b) to the CAA.[5] To implement this 2005 CAA amendment, EPA promulgated the 2007 Exceptional Events Rule.[6] The 2007 Exceptional Events Rule created a regulatory process codified at 40 CFR parts 50 and 51 (§§ 50.1, 50.14 and 51.930). These regulatory sections, which superseded EPA's previous guidance on handling data influenced by events, contain definitions, procedural requirements, requirements for air agency demonstrations, criteria for EPA's approval of the exclusion of event-affected air quality data from the data set used for regulatory decisions, and requirements for air agencies to take appropriate and reasonable actions to protect public health from exceedances or violations of the NAAQS. In 2016, EPA promulgated a comprehensive revision to the 2007 Exceptional Events Rule.[7] Under the Exceptional Events Rule, for example, if a state demonstrates to EPA's satisfaction that emissions from a wildfire smoke event caused a specific air pollution concentration in excess of the PM_{10} NAAQS at a particular air quality monitoring location and otherwise satisfies the requirements of 40 CFR 50.14, EPA must exclude that data from use in determinations of exceedances and violations.[8]

The Oakridge NAA Exceptional Event Demonstrations and Concurrences

The CAA allows for the exclusion of air quality monitoring data from design value calculations when there are NAAQS exceedances caused by events, such as wildfires, that meet the criteria for an exceptional event identified in EPA's Exceptional Events Rule at 40 CFR 50.1, 50.14 and 51.930. For the purposes of this proposed action, on July 22, 2021, ODEQ submitted an exceptional events demonstration for the purpose of showing that PM_{10} concentrations recorded at the Oakridge Willamette Center monitor from September 11, 2020 through September 16, 2020 were influenced by wildfires. EPA concurred on this request on April 1, 2022.

EPA found that Oregon's demonstration met the Exceptional Events Rule criteria and determined that the wildfire event had regulatory significance for purposes of calculating the area's most recent design value to demonstrate the area continues to attain the standard in order to redesignate the area to attainment for the PM_{10} NAAQS. As such, EPA proposes to take final regulatory action on the concurred dates, as detailed in the docket for this action, as exceptional events to be removed from the data set used for regulatory purposes. For this proposed action, EPA will rely on the calculated values that exclude the event-influenced data for the purpose of demonstrating continued attainment of the 1987 24-hour PM_{10} NAAQS. Further details on Oregon's analyses and EPA's concurrences can be found in the docket for this regulatory action.

While EPA may agree with Oregon's request to exclude event influenced air quality monitoring data from regulatory decisions, these regulatory actions require EPA to provide an opportunity for public comment on the claimed exceptional event and all supporting data prior to EPA taking final agency action. This proposed action provides the public with an opportunity to comment on the claimed exceptional event, all supporting documents and EPA's concurrence with Oregon's request.

Evaluation of Current Attainment

As noted previously, on July 26, 2001, EPA finalized a Determination of Attainment for the Oakridge NAA based upon quality-assured and certified ambient air quality monitoring data for the 1998–2000 design value period (66 FR 38947). There were no exceedances of the 24-hour PM_{10} standard during this period. Therefore, the expected exceedance rate was 0.0, which demonstrates attainment of the 24-hour PM_{10} NAAQS.

For this proposed action, EPA reviewed the most recent PM_{10} ambient air monitoring data in the Oakridge area for the monitoring design value period of 2018–2020. Consistent with the requirements at 40 CFR part 50, this ambient monitoring data in EPA's AQS has been quality-assured, quality-controlled and certified by ODEQ. The 24-hour PM_{10} design value for 2020 was 0.7, therefore, the average number of expected exceedances averaged over a three-year period is less than or equal to one.[9] Thus, EPA concludes that the Oakridge area continues to demonstrate continued attainment of the 1987 24-hour PM_{10} NAAQS during the three-year period ending on December 31, 2020.

B. Applicable Requirements Under Section 110 and Part D of the CAA

Section 107(d)(3)(E)(ii) and (v) of the CAA require EPA to determine that the area has a fully approved applicable SIP under section 110(k) that meets all applicable requirements under section 110 (general SIP requirements) and part D (SIP requirements for nonattainment areas) for the purposes of redesignation. We interpret this to mean that, for a redesignation request to be approved, the state must have met all requirements that applied to the subject area prior to, or at the time of, submitting a complete redesignation request. EPA may rely on prior SIP approvals in approving a redesignation request[10] as well as any additional measure it may approve in conjunction with a redesignation action.

1. CAA Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP. These requirements include, but are not limited to the following: (1) Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; (2) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (3) implementation of a source permit program; (4) provisions for the implementation of part C requirements (PSD); (5) provisions for the implementation of part D requirements for NSR permit programs; (6) provisions for air pollution modeling; and (7) provisions for public and local agency participation in planning and emission control rule development.[11]

We note that SIPs must be fully approved only with respect to applicable requirements for purposes of redesignation in accordance with section 107(d)(3)(E)(ii). Similarly, EPA believes that the other CAA section 110(a)(2) (and part D) requirements that

[5] Under CAA section 319(b), an exceptional event means an event that (i) affects air quality; (ii) is not reasonably controllable or preventable; (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and (iv) is determined by EPA under the process established in regulations promulgated by EPA in accordance with section 319(b)(2) to be an exceptional event. For the purposes of section 319(b), an exceptional event does not include (i) stagnation of air masses or meteorological inversions; (ii) a meteorological event involving high temperatures or lack of precipitation; or (iii) air pollution relating to source noncompliance.

[6] 72 FR 13560 (March 22, 2007).

[7] 81 FR 68216 (October 3, 2016). We refer herein to the 2016 revision as the ''Exceptional Events Rule.''

[8] 40 CFR 50.14(b)(4).

[9] As noted above, EPA excluded data for September 11, 2020 through September 16, 2020 from this design value because the Agency determined concentrations recorded on those dates satisfied the requirements of the Exceptional Events Rule.

[10] Calcagni Memo, 3; *Wall* v. *EPA,* 265 F.3d 426, 438 (6th Cir. 2001); and *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–990 (6th Cir. 1998).

[11] *See* the General Preamble for further explanation of these requirements. 57 FR 13498 (April 16, 1992).

are not connected with nonattainment plan submittals and not linked with an area's attainment status are not applicable requirements for purposes of redesignation because the area will still be subject to these requirements after it is redesignated. EPA considers the CAA section 110(a)(2) (and part D) requirements that relate to a particular nonattainment area's designation and classification as the relevant measures to evaluate in reviewing a redesignation request. This approach is consistent with EPA's existing policy on applicability of the conformity SIP requirement for redesignations.[12]

EPA has reviewed the Oregon SIP and concludes that it meets the general SIP requirements under section 110(a)(2) of the CAA to the extent they are applicable for the purposes of redesignation.[13] On several occasions, Oregon has submitted, and EPA has approved, provisions of Oregon's SIP as demonstrating compliance with CAA section 110(a)(2) requirements.[14] These requirements are, however, statewide requirements that are not linked to the PM_{10} nonattainment status of the Oakridge NAA. In addition, there are no outstanding or disapproved applicable SIP submittals with respect to the Oakridge portion of the SIP that would prevent redesignation of the Oakridge NAA for the PM_{10} NAAQS. Therefore, we conclude that ODEQ and LRAPA have met all general SIP requirements for the Oakridge NAA that are applicable for purposes of redesignating the area to attainment of the PM_{10} NAAQS.

2. Part D of Title I Requirements

Before a PM_{10} nonattainment area may be redesignated to attainment, the state must have fulfilled the applicable requirements of part D of Title I of the CAA, which sets forth the basic nonattainment plan requirements applicable to all areas designated nonattainment. The general requirements are followed by a series of subparts specific to each pollutant. Subpart 1 of part D establishes the general requirements applicable to all NAAs, while subpart 4 of part D establishes specific requirements applicable to PM_{10} NAAs. The General Preamble provides that the applicable requirements of subpart 1 (CAA section 172) are, in relevant part, 172(c)(3) (emissions inventory), 172(c)(5) (new source review permitting program), 172(c)(7) (the applicable provisions of section 110(a)(2)), and 172(c)(9) (contingency measures). It is also worth noting that we interpreted the requirements of section 172(c)(2) (RFP) and 172(c)(6) (other measures) as being irrelevant to a redesignation request because they only have meaning for an area that is not attaining the standard. *See* Calcagni Memo and the General Preamble, 57 FR 13530, 13564, dated April 16, 1992. Finally, Oregon has not sought to exercise the options that would trigger CAA section 172(c)(8) (equivalent techniques). Thus, these provisions are also not relevant to this redesignation request.

The requirements of CAA section 172(c) and 189(a) regarding attainment of the PM_{10} NAAQS, and the requirements of section 172(c) regarding RFP, imposition of RACM, the adoption of contingency measures, and the submittal of an emission inventory have been satisfied through our March 15, 1999, approval of the Oakridge PM_{10} SIP (64 FR 12751). Additionally, on July 26, 2001, EPA published a finding of attainment for the Oakridge PM_{10} area (66 FR 38947). EPA found that the Oakridge NAA attained the 24-hour PM_{10} NAAQS by the moderate PM_{10} attainment date of December 31, 2000.

CAA section 172(c)(4) requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and CAA section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA first approved the requirements of the part D, subpart 1 NSR permit program for LRAPA on December 27, 2011 (76 FR 80747, 80748). Subsequently, LRAPA revised its rules to meet additional part D, subpart 4 NSR requirements promulgated by EPA (81 FR 58010, August 24, 2016) and to align with ODEQ's rules.[15] EPA approved LRAPA's rules on October 5, 2018 (83 FR 50274).

Once the Oakridge NAA is redesignated to attainment, the prevention of significant deterioration (PSD) requirements of part C of the Act will apply. LRAPA's PSD regulations are codified in Title 29 (Designation of Air Quality Areas), Title 38 (New Source Review) and Title 50 (Ambient Air Standards and PSD Increments) in conjunction with other provisions including but not limited to LRAPA's rules in Titles 12, 31, 34, 35, 40, and 42. We most recently approved revisions to LRAPA's PSD program on October 5, 2018 (83 FR 50274). EPA finds that LRAPA's PSD provisions meet all applicable Federal requirements for any area designated unclassifiable or attainment, and these provisions will become fully effective in the Oakridge area upon redesignation to attainment.

CAA section 172(c)(7) requires the SIP to meet the applicable provisions of CAA section 110(a)(2). As noted above, we find that the Oregon SIP meets the CAA section 110(a)(2) applicable requirements. For purposes of redesignation to attainment for the 1987 24-hour PM_{10} NAAQS, EPA proposes to find that LRAPA has met all the applicable SIP requirements under part D of Title I of the CAA in accordance with section 107(d)(3)(E)(v) of the CAA.

3. Fully Approved SIP Under CAA Section 110(k)

Section 110(k) of the CAA sets out provisions governing EPA's review of SIP submittals. In order for an area to qualify for redesignation, the SIP for the area must be fully approved under section 110(k) of the CAA. As discussed in Sections III.B.1 and III.B.2 of this document, for purposes of redesignation to attainment for the 1987 24-hour PM_{10} NAAQS, EPA has fully approved all applicable requirements of Oregon's SIP for the Oakridge area in accordance with CAA section 110(k). Therefore, the criterion for redesignation, set forth at CAA section 107(d)(3)(E)(ii), is satisfied.

C. Improvement in Air Quality Due to Permanent and Enforceable Measures

In order to approve a redesignation to attainment, section 107(d)(3)(E)(iii) of the CAA requires EPA to determine that the improvement in air quality is due to emissions reductions that are permanent and enforceable, and that the improvement is from the implementation of the applicable SIP, implementation of applicable Federal air pollution control regulations, and other permanent and enforceable reductions.

The Oakridge 1996 attainment plan addressed attainment planning requirements for the Oakridge moderate NAA, including control measures to satisfy the RACM requirement and a demonstration that attainment of the PM_{10} NAAQS would be achieved by the required dates. The federally-approved 1996 attainment plan included woodstove change-outs, a voluntary residential woodsmoke curtailment program, commitment to reduce winter road sanding, and the paving of unpaved roads to reduce emissions of

[12] *See* 75 FR 36023, 36026 (June 24, 2010) and citations within.

[13] The LRAPA portion of the federally-approved Oregon SIP can be viewed at *https://www.epa.gov/sips-or/epa-approved-regulations-oregon-sip.*

[14] *See, e.g.,* 83 FR 24034 (May 24, 2019) and 84 FR 26347 (June 6, 2019).

[15] *See* 40 CFR 51.160, 51.161, 51.165, and 51.166. *See also* EPA's proposed approval of Oregon nonattainment NSR program (March 22, 2017, 82 FR 14654, 14663) and EPA's final approval (October 11, 2017, 82 FR 47122).

PM_{10} in the Oakridge NAA. EPA's approval of this SIP made these control strategies federally enforceable.

The historical PM_{10} air pollution problem in the Oakridge area has been emissions from residential wood combustion. Since 1993, as funding allowed, the Oakridge area has experienced emission reduction benefits from changing-out uncertified woodstoves for cleaner burning and more efficient home heating units. More recently, EPA approved the Oregon Heat Smart Program [16] and the Oakridge City Air Pollution Control Ordinance 920 (Oakridge Ordinance 920) [17] into the Oregon SIP. Both prohibit the installation and ban the sale of non-EPA-certified devices in new or existing buildings. In addition to the initial woodstove change-outs provided for in the 1996 attainment plan, these SIP strengthening control strategies provide for permanent and enforceable PM_{10} reductions in the Oakridge NAA.

Since 1989, LRAPA, in cooperation with the City of Oakridge, has implemented a residential woodsmoke curtailment program in the Oakridge NAA. Oakridge Ordinance 815, State effective August 26, 1996 and federally-approved in the 1999 attainment plan, prohibited visible emission from a solid fuel burning device during a Red Advisory (when the PM_{10} levels are forecast by LRAPA to be greater than or equal to 120 $\mu g/m^3$) unless granted a sole source or economic need exemption. Oakridge Ordinance 815 is superseded by the federally-approved Oakridge Ordinance 920, which is more protective of the PM_{10} NAAQS. In addition to the existing residential woodsmoke curtailment program, Oakridge Ordinance 920 provides further strengthening of the control measures while maintaining the integrity of the prior ordinance.

Oakridge Ordinance 920 strengthens the SIP by prohibiting the burning of any fuel other than ''seasoned wood,'' which is defined as any species of wood that has been sufficiently dried to contain 20 percent or less moisture by weight, and prohibiting the burning of specified materials such as plastic, rubber products, petroleum-treated materials and other materials which normally emit dense smoke, noxious odors, or hazardous air contaminants in a solid fuel burning device. EPA proposes to remove the City of Oakridge Ordinance 815 from the Oregon SIP because it is superseded by the federally-approved Oakridge Ordinance 920, which strengthens the PM_{10} SIP and ensures the woodstove curtailment program continues to be permanent and enforceable.

The second largest source of PM_{10} emissions in the Oakridge NAA is road dust, of which winter road sanding and unpaved road dust are contributors. To reduce road sanding emissions the Oregon Department of Transportation (ODOT) has been using an anti-icing chemical, calcium magnesium acetate (CMA), instead of grit, within the City of Oakridge since 1995. ODOT continues to commit to using these chemicals into the future (*See* the September 20, 2021, letter from Jim Gamble, District 5 Manager, ODOT, included in the docket for this action). In addition, between 1991 and 1995 all of Oakridge's unpaved roads, approximately 2.5 miles, and numerous unpaved commercial driveways and parking lots were paved.[18]

Based on the foregoing evaluation of these control measures, EPA proposes to determine that the improvement in air quality is reasonably attributable to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and other permanent and enforceable reductions. Therefore, the criterion for redesignation set forth at CAA section 107(d)(3)(E)(iii) is satisfied.

D. Fully Approved Maintenance Plan

CAA section 107(d)(3)(E)(iv) requires that, for a nonattainment area to be redesignated to attainment, EPA must fully approve a maintenance plan for the area as meeting the requirements of CAA section 175A. The maintenance plan must demonstrate continued attainment of the relevant NAAQS in the area for at least 10 years after our approval of the redesignation. Eight years after redesignation, the state must submit a revised maintenance plan demonstrating attainment for the 10 years following the initial 10-year period. The maintenance plan must also contain a contingency plan to ensure prompt correction of any violation of the NAAQS that occurs after redesignation of the area. *See* CAA sections 175A(a), (b) and (d). The Calcagni Memo provides additional guidance on the content of a maintenance plan, stating that a maintenance plan should include the following elements: (1) An attainment emissions inventory; (2) a maintenance demonstration showing attainment for 10 years following redesignation; (3) a commitment to maintain and operate an appropriate air quality monitoring network; (4) verification of continued attainment; and (5) a contingency plan to prevent or correct future violations of the NAAQS. In this proposed action, EPA will review requirements (3) and (4) together as part of our evaluation of LRAPA's maintenance plan for the Oakridge area.

In conjunction with Oregon's request to redesignate the Oakridge area to attainment, Oregon submitted a SIP revision to provide for maintenance of the 1987 24-hour PM_{10} NAAQS through 2035. EPA proposes to approve LRAPA's PM_{10} maintenance plan for the Oakridge area. The following paragraphs describe how each of the maintenance plan elements are addressed in the maintenance plan.

1. Attainment Inventory

As discussed in the General Preamble (*See* 57 FR 13498, April 16, 1992) and the Calcagni Memo, PM_{10} maintenance plans should include an attainment emission inventory to identify the level of emissions in the area sufficient to maintain the PM_{10} NAAQS. The maintenance plan attainment inventory should be consistent with EPA's emissions inventory requirements and most recent guidance on emissions inventories for nonattainment areas available at the time and should represent emissions during the time period associated with the monitoring data showing attainment.[19] The inventory must also be comprehensive, including emissions from stationary point sources, area sources, mobile sources, and must be based on actual emissions during the appropriate season, if applicable.

The Oakridge PM_{10} maintenance plan includes a 2015 PM_{10} attainment emission inventory (2015 attainment inventory) based on typical season and worst-case day actual emissions from all direct primary PM_{10} sources (point, area, on-road mobile and nonroad mobile sources.[20] [21] The year 2015 is

[16] A statewide mandate approved by EPA on October 11, 2017 (82 FR 47122).

[17] *See* 83 FR 5537, February 8, 2018.

[18] *See* 64 FR 12751 (March 15, 1999).

[19] *See* Calcagni Memo at 8.

[20] ODEQ's PM_{10} emission inventory includes emissions within the larger Oakridge-Westfir $PM_{2.5}$ nonattainment area boundary (not the smaller Oakridge urban growth boundary). EPA believes this is appropriate in this instance (except for when calculating the motor vehicle emissions) because the Oakridge PM_{10} nonattainment area encompasses the vast majority of the population and activity within the Oakridge-Westfir $PM_{2.5}$ NAA.

[21] PM_{10} precursor emissions should also be included depending upon the contribution of the secondarily-formed particulate matter to high ambient PM_{10} concentrations in the area. In this instance, an inventory of PM_{10} precursor emissions is not required because PM_{10} precursor controls were not relied upon to achieve attainment of the PM_{10} NAAQS in the Oakridge planning area (64 FR 12751, March 15, 1999), nor are they relied upon

representative of the level of emissions during the time period when the Oakridge area's monitoring data shows attainment of the 1987 24-hour PM_{10} NAAQS. The 2015 maintenance plan attainment inventory is based on emission reduction strategies that were implemented as of 2015. These are summarized in Table 1, along with future year projected emissions for a 2035 ''horizon year'' (a future year at least 10 years from the approval date of the maintenance plan), and two interim years of 2025 and 2030.

Oregon's 2015 attainment inventory relies on methods and assumptions presented in detail in Appendix II of the Oakridge PM_{10} maintenance plan (''Emision Inventory for 2015 Base Year''). The 2015 attainment inventory is based on typical season and worst-case day (episodic) emissions. The typical season day emissions represent an average daily emission value occurring from November 1 through the end of February. This four-month time period is considered to be the particulate matter season and is when the PM_{10} standard has historically been exceeded. EPA considers the preparation of the typical season day inventory and worst-case day inventory, as opposed to an annual average daily inventory, appropriate given that the elevated PM_{10} concentrations in Oakridge exhibit clear seasonal or episodic patterns. The worst-case day emissions represent a day during the PM season when emissions generating activity is at its highest due to meteorological factors like temperature. However, residential woodburning and other area source emissions on worst-case days are lower than on typical season days in the inventory due to woodburning curtailments and outdoor burning bans.

Residential wood combustion emissions from woodstoves, fireplaces and pellet stoves continue to be the major source of PM_{10} emissions for both typical season days and worst-case winter days contributing to exceedances of the NAAQS.

TABLE 1—OAKRIDGE PM_{10} MAINTENANCE PLAN EMISSIONS INVENTORIES

[In pounds per day]

Source category	2015 Attainment	2025 Interim	2030 Interim	2035 Maintenance	Difference from 2015 and 2035
PM_{10} Typical Season Day					
Point	0.0	8.0	8.0	8.0	8.0
Area	444.8	364.2	364.0	363.5	−81.3
On-road	142.1	131.0	133.2	132.8	−9.3
Nonroad	2.9	2.9	2.9	2.9	0.0
Total	589.8	506.1	508.1	507.2	−82.6
PM_{10} Worst-Case Day					
Point	0.0	13.7	13.7	13.7	13.7
Area	334.5	250.9	233.8	216.5	−118.0
On-road	158.5	144.1	146.5	146.0	−12.5
Nonroad	2.9	2.9	2.9	2.9	0
Total	495.9	411.6	396.9	379.1	−116.8

Based on our review of the documentation provided in the maintenance plan, we propose to find that the 2015 direct PM_{10} attainment emission inventory is based on reasonable assumptions and methodologies, and that the inventory is comprehensive and based on the most accurate and current information available to LRAPA at the time it was developed. Based on our review of the 2015 emissions inventory Oregon provided in its January 13, 2022 submittal, we propose to find that LRAPA prepared an adequate attainment inventory for the Oakridge area.[22]

2. Maintenance Demonstration

CAA section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for maintenance of the NAAQS for a period of at least 10 years following redesignation. A state can make this demonstration by either showing that future emissions of a pollutant or its precursors will not exceed the level of the attainment (base year) inventory, or by modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS.[23]

In its maintenance demonstration for the Oakridge area, LRAPA elected to demonstrate maintenance of the PM_{10} NAAQS for at least 10 years following redesignation using the attainment year inventory method. LRAPA developed projected inventories, provided in Table 1 of this document, to show that the Oakridge area will remain in attainment through the year 2035. These projected inventories, covering interim years 2025 and 2030 and a horizon year of 2035, show that future emissions of direct PM_{10} throughout the nonattainment area will remain at or below the 2015 attainment emissions for the 1987 24-hour PM_{10} NAAQS.

The projected emissions inventories in the Oakridge PM_{10} maintenance plan address four major source categories: Point, area, on-road mobile and nonroad mobile. Oregon estimated future year emission inventories using the latest socioeconomic growth indictors and applying emissions reduction benefits from adopted control strategies when

to demonstrate maintenance of the NAAQS. While not required, the maintenance plan includes an inventory of PM_{10} precursor emissions in Appendix II (''PM_{10} Emission Inventory for 2015 Base Year'').

[22] *See* ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations,'' May 2017, available at *https://www.epa.gov/sites/default/files/2017-07/documents/ei_guidance_may_2017_final_rev.pdf.*

[23] *See* Calcagni Memo, pages 9–10.

appropriate. A detailed description of the 2015 attainment year inventory and the 2025, 2030 and 2035 projected inventories can be found in Appendix III of LRAPA's January 13, 2022, PM_{10} maintenance plan submittal, which is in the docket for this action.

As discussed in the Oakridge PM_{10} maintenance plan, direct PM_{10} emissions estimates for stationary point sources reflect actual emissions for both industrial point sources in Oakridge. The Oakridge Sand & Gravel ready-mix concrete plant and rock crusher did not operate in Oakridge in 2015, resulting in actual 2015 emissions that were zero. In addition, the ready-mix concrete plant air discharge permit was terminated on January 24, 2014, resulting in zero emissions in the 2015 and projected year emission inventories. Future year emissions were therefore based on the January 2011 PM_{10} emissions at this source.

Areawide sources occur over a wide geographic area with the most significant emissions resulting from residential wood combustion sources such as fireplaces, woodstoves and pellet stoves. These residential wood heating devices are commonly used to heat homes in Oakridge since natural gas is not available in this area. The permanent and enforceable residential wood combustion control strategies are discussed in Section III.C. of this document. The only other area source category with potentially significant emissions is outdoor burning, which is banned in Lane County from November-February. Emissions for these categories are derived using various surveys, emission factors and other methodologies.

Emissions from on-road mobile sources (exhaust, brake wear and tire wear), which include passenger vehicles, buses, and trucks, were estimated using MOVES2014a. Traffic growth in Vehicle-Miles Traveled (VMT) was based on transportation modeling by the Lane Council of Governments (LCOG) and ODOT. LRAPA confirmed re-entrained road dust calculations for both paved and unpaved roads using AP–42 protocols. Federal control measures included in the MOVES2014a modeling are all Federal measures that affect the fleets and fuels used in future years once implemented by EPA.

The nonroad emissions from railroads were calculated using the EPA NONROAD2008a emission protocol. The National Emissions Inventories (NEIs) for Lane County indicate a significant decrease in locomotive emissions from 2008 to 2014 (42.63 tons/year and 19.62 tons/year, respectively). The 2015 PM_{10} railroad emissions have been adjusted to reflect the locomotive emission reductions as seen in the 2014 NEI data. Future year emissions are based on the adjusted 2014 and 2017 NEI data. All other Oakridge nonroad mobile sources are categorized by LRAPA as insignificant during the PM_{10} winter season.

EPA has reviewed the documentation provided by Oregon for developing the projected 2025, 2030 and 2035 emissions inventories for the Oakridge PM_{10} NAA. Based on our review, EPA finds that the projected inventories were developed using appropriate procedures, comprehensively address all source categories in the Oakridge area, and sufficiently account for PM_{10} projected actual emissions. These inventories indicate a decrease in PM_{10} emissions throughout the maintenance period. Therefore, EPA proposes to determine that the projected emissions inventories in the maintenance plan sufficiently demonstrate that the Oakridge PM_{10} area will continue to attain the 1987 24-hour PM_{10} standard throughout the maintenance period.

3. Monitoring Network and Verification of Continued Attainment

Once a nonattainment area has been redesignated to attainment, the state must continue to operate an appropriate air quality monitoring network, in accordance with 40 CFR part 58, to verify the attainment status of the area. The maintenance plan should contain provisions for continued operation of air quality monitors that will provide such verification.

LRAPA notes in the Oakridge PM_{10} maintenance plan that it currently operates a regulatory monitor (the Willamette Center monitor since 1989) in the Oakridge NAA. LRAPA commits to continue operating a regulatory monitoring network, in accordance with 40 CFR part 58 and the Oregon SIP through the year 2035 in order to verify continued attainment of the PM_{10} NAAQS and track the progress of the maintenance plan. LRAPA also states that it will continue to operate the PM_{10} monitoring network in accordance with the approved Annual Monitoring Network Plan (ANP). Any modification to the monitoring network will be done in consultation with ODEQ and with the approval of EPA Region 10 (*See* 40 CFR 58.14(b)). EPA will work with ODEQ and LRAPA each year through the air monitoring network review process to determine the adequacy of the monitoring network.[24]

Oregon remains obligated to continue to quality-assure monitoring data and enter all data into AQS in accordance with Federal guidelines. LRAPA will review the air monitoring results each year to verify continued attainment. LRAPA will determine annually if exceptional events influenced the continued attainment of the 1987 24-hour PM_{10} NAAQS and need to be documented. If needed, ODEQ and LRAPA will coordinate and provide exceptional events documentation to EPA Region 10 for review.

It should be noted that LRAPA included in the Oakridge maintenance plan a discussion on the use of $PM_{2.5}$ monitoring as a surrogate for PM_{10} monitoring in the future. *See* Section 4.2 of the Oakridge maintenance plan. Since any change to the monitoring network would occur in the future, EPA is not proposing to approve LRAPA discontinuing the PM_{10} monitor, nor is EPA making a determination whether the use of a $PM_{2.5}$ surrogate monitor would be appropriate or consistent with 40 CFR part 58 requirements as part of this action.

EPA proposes to determine that the Oakridge PM_{10} maintenance plan contains adequate provisions for continued operation of an air quality monitoring network and a commitment to annually verify continued attainment of the 1987 24-hour PM_{10} NAAQS for the Oakridge area.

4. Contingency Plan

CAA section 175A(d) requires that a maintenance plan also include contingency provisions, as necessary, to promptly correct any violation of the NAAQS that occurs after redesignation of the area to attainment. For the purposes of CAA section 175A, a state is not required to have fully adopted contingency measures that will take effect without further action by the state in order for the maintenance plan to be approved. However, the contingency plan is an enforceable part of the SIP and should ensure that contingency measures are adopted expeditiously once they are triggered. The maintenance plan should discuss the measures to be adopted and a schedule and procedure for adoption and implementation. The contingency plan must require that the state will implement all measures contained in the part D nonattainment plan for the area prior to redesignation. The state

[24] *See* EPA's February 22, 2022 approval of Oregon's 2021 Annual Monitoring Network Plan, in the docket for this action.

should also identify the specific indicators, or triggers, which will be used to determine when the contingency plan will be implemented.[25]

The Oakridge PM_{10} maintenance plan outlines the procedures for the adoption and implementation of contingency measures to further reduce emissions should a violation of the PM_{10} NAAQS or the 2006 24-hour $PM_{2.5}$ NAAQS (35 $\mu g/m^3$) occur. It is expected that the $PM_{2.5}$ NAAQS would be exceeded before the PM_{10} NAAQS, thus more quickly triggering the implementation of the contingency measures in the maintenance plan. If there is a violation of either standard, after consideration of any exceptional events, the following contingency strategies, or equivalent, will be implemented by LRAPA and the City of Oakridge:

- Stricter green-yellow-red advisory program,[26] with more red advisory days each winter, by reducing the red advisory thresholds by 3 $\mu g/m^3$ PM_{10}. This is projected to increase the average number of potential red advisory days by three to five additional days per year.
- Prohibition of fireplace use on yellow advisory days (in addition to the existing prohibition on red advisory days).

While these measures do not need to be fully adopted by LRAPA prior to the occurrence of a NAAQS violation, LRAPA commits to adopting and implementing the necessary contingency measures as expeditiously as possible, but not later than one year after a violation based on confirmed quality assured data.

LRAPA will evaluate all appropriate data including air quality data, meteorological data, evaluation of wood smoke programs and information on unusual weather events (*e.g.,* wildfires or winter power outages) and other data to determine the cause of the violation. LRAPA will perform this evaluation within three months of the determination of a violation. Where appropriate, LRAPA will follow EPA's exceptional events rules and guidance if it is determined that an exceptional event contributed to the violation.[27]

Based on our analysis of Oregon's submittal, we propose to find that the contingency measure provisions provided in the Oakridge PM_{10} maintenance plan are sufficient and meet the requirements of CAA section 175A(d).

E. Transportation Conformity and Motor Vehicle Emissions Budgets

Transportation conformity is required by CAA section 176(c). EPA's conformity rule at 40 CFR part 93, subpart A requires that transportation plans, programs, and projects conform to SIPs and establishes the criteria and procedures for determining whether or not they conform. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS. Thus, EPA's conformity rule requires a demonstration that emissions from a Metropolitan Planning Organization's (MPO's) Regional Transportation Plan and Transportation Improvement Program, involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval, are consistent with the MVEB(s) contained in a control strategy SIP revision or maintenance plan (40 CFR 93.101, 93.118, and 93.124). A MVEB is the level of mobile source emissions of a pollutant relied upon in the attainment or maintenance demonstration to attain or maintain compliance with the NAAQS in the nonattainment or maintenance area.

PM_{10} maintenance plan MVEBs are generally established for specific years and specific pollutants or precursors.[28] The maintenance plan submittal should identify MVEBs for transportation related PM_{10} emissions (motor vehicle emissions from tailpipe, brake wear, tire wear and re-entrained road dust) in the last year of the maintenance period. Budgets may also be specified for additional years during the maintenance period.

It should be noted that Oakridge is considered an isolated rural nonattainment area within the meaning of 40 CFR 93.109(g), so transportation conformity determinations are only required when a non-exempt Federal Highway Administration or Federal Transit Administration funded project is funded or approved.[29]

With respect to previously established MVEBs, we note for the 1996 attainment plan, Oregon had previously adopted PM_{10} MVEBs for 2003. These budgets were 178.8 pounds per day of direct PM_{10}. This budget has continued to apply for conformity determinations since 2003. In addition, as determined in the 1996 attainment plan approval, major sources of PM_{10} precursors do not contribute significantly to PM_{10} levels in excess of the PM_{10} NAAQs in the Oakridge NAA. Therefore, the Oakridge PM_{10} maintenance plan includes direct PM_{10} MVEBs that reflect the total on-road PM_{10} emissions for the attainment year (2015), and the projected PM_{10} emissions for two interim years (2025 and 2030) and the last year of the maintenance plan (2035). *See* Table 2, below.

The MVEBs reflect the total on-road PM_{10} worst-case day emissions (a sum of primary exhaust, brake wear, tire wear and re-entrained paved and unpaved road dust), plus a portion of the available safety margin to accommodate technical uncertainties due to model updates and inputs into the EPA MOVES model and travel forecasting models as well as potential changes to regional transportation plans. A safety margin is the amount by which the total projected PM_{10} emissions from all sources are less than the total emissions that would satisfy the NAAQS for the 2015 base year. With the safety margin applied to the future year MVEB, the budgets still demonstrate maintenance of the 1987 24-hour PM_{10} NAAQS.

Oregon used the Motor Vehicle Emissions Simulator model, MOVES2014a, during the development of the maintenance plan and executed it with locally developed inputs representative of wintertime calendar year 2015 conditions and future projections in order to appropriately calculate the budgets. MOVES2014a was the accepted model when this work began. EPA recently released MOVES3, but since sufficient work had taken place on this SIP with MOVES2014a, we are accepting that mobile model in this submittal (86 FR 1106, 1108, January 7, 2021). Traffic growth in VMT for the Oakridge NAA is based on transportation modeling by Lane County, LCOG and ODOT. The mobile source emissions, in total, were modeled to steadily decrease between 2015 and 2035 as a result of cleaner vehicles and cleaner fuels. The MVEBs are based on the control measures in the

[25] *See* Calcagni Memo at 12.

[26] LRAPA implements an advisory system that designates days as green, yellow, or red when 24-hour PM levels reach certain designated thresholds. During a red advisory day, LRAPA prohibits the use of any solid fuel space heating device that emits visible emissions into the air outside of the building housing the device unless a specific exemption has been granted.

[27] Treatment of Data Influenced by Exceptional Events, October 3, 2016, 81 FR 68216.

[28] Transportation-related emissions of volatile organic compounds (VOCs) or nitrogen oxides (NO_X) must also be specified in PM_{10} areas if EPA or the state find that transportation-related emissions of one or both of these precursors within the nonattainment area are a significant contributor to the PM_{10} nonattainment problem and has so notified the MPO and the U.S. Department of Transportation (DOT), or the applicable SIP revisions or SIP revision submittal establishes an approved or adequate budget for such emissions as part of the reasonable further progress, attainment or maintenance strategy. 40 CFR 93.102(b)(2)(iii). Neither of these conditions apply to the Oakridge PM_{10} nonattainment area.

[29] *See* 40 CFR 93.109(g).

maintenance plan and consistent with maintaining the PM_{10} NAAQS.

The mobile source emissions budgets for the years 2015, 2025, 2030 and 2035 are provided in Table 2 of this proposed action. According to EPA's conformity rule, the emissions budget acts as a ceiling on emissions in the year for which it is defined or until a SIP revision modifies the budget.[30]

TABLE 2—PM_{10} MVEBS FOR THE OAKRIDGE PM_{10} NAA

Motor vehicle emissions budgets	Year			
	2015	2025	2030	2035
PM_{10} (lbs/day)	138.9	147.4	156.8	164.7

For MVEBs to be approvable, they must meet, at a minimum, EPA's adequacy criteria (40 CFR 93.118(e)(4)). EPA's process for determining adequacy of a budget consists of three basic steps: (1) Notifying the public of a SIP submittal; (2) providing the public the opportunity to comment on the budget during a public comment period; and (3) making a finding of adequacy or inadequacy. The process for determining the adequacy of a submitted budget is codified at 40 CFR 93.118(f). EPA can notify the public by either posting an announcement that EPA has received SIP budgets on EPA's adequacy website (40 CFR 93.118(f)(1)), or via a **Federal Register** notice of proposed rulemaking when EPA reviews the adequacy of an implementation plan budget simultaneously with its review and action on the SIP itself (40 CFR 93.118(f)(2)).

Today, we are notifying the public that EPA will be reviewing the adequacy of the 2015, 2025, 2030 and 2035 budgets in the Oakridge PM_{10} maintenance plan. The public has a 30-day comment period as described in the **DATES** section of this notice. After this comment period, EPA will indicate whether the budgets are adequate via the final rulemaking on this proposed action or on the adequacy website, according to 40 CFR 93.118(f)(2)(iii). The details of EPA's evaluation of the budget for compliance with the budget adequacy criteria of 40 CFR 93.118(e) are provided in a separate memorandum included with the docket for this rulemaking.[31] As noted earlier, the public comment period for EPA's adequacy finding will be concurrent with the public comment period for this proposed action on the Oakridge PM_{10} maintenance plan.

Based on the information presented in the Oakridge PM_{10} maintenance plan and our adequacy review to date, we propose to find that Oregon has evaluated the appropriate pollutants and appropriately established MVEBs for direct PM_{10} emissions. EPA has reviewed the Oakridge PM_{10} maintenance plan's MVEBs and found them to be consistent with the control measures in the SIP and consistent with maintenance of the 1987 24-hour PM_{10} NAAQS within the Oakridge area through 2035. We propose to approve the MVEBs in the Oakridge PM_{10} maintenance plan as meeting the requirements of the CAA and EPA regulations.

F. State Rule Changes To Reflect the Redesignation

Oregon adopted maintenance plans for both the Oakridge PM_{10} area and Oakridge $PM_{2.5}$ area in the same state rulemaking package and submitted them as a single SIP submittal to EPA. This single submittal includes changes to LRAPA rules to reflect the anticipated redesignation of both areas. Today's action addresses the Oakridge PM_{10} area, and we are addressing the Oakridge $PM_{2.5}$ area in a separate action. In today's action EPA is proposing to approve revisions to LRAPA's Title 29 *Designation of Air Quality Areas,* Section 29–0030(1) *Designation of Nonattainment Areas* and Section 29–0040(2)(b) *Designation of Maintenance Areas.* These revisions will remove the Oakridge PM_{10} nonattainment areas from the list of PM_{10} nonattainment areas and add them to the list of PM_{10} maintenance areas within the federally-approved Oregon SIP.[32]

IV. Proposed Action

EPA proposes to redesignate the Oakridge, Oregon PM_{10} NAA, and proposes to approve the associated maintenance plan for the area. If this proposal is finalized, the designation status of the Oakridge, Oregon PM_{10} NAA, under 40 CFR part 81 will be revised to attainment upon the effective date of that final action.

EPA proposes to approve and incorporate by reference into the Oregon SIP, the submitted revisions to LRAPA Title 29 Sections 29–0030(1) and 29–0040(2)(b) state effective November 18, 2021. EPA also proposes to approve the State's request to remove from incorporation by reference City of Oakridge Ordinance 815, state effective August 15, 1996.

In addition, EPA proposes to take final agency action on Oregon's exceptional event demonstration for the Oakridge $PM_{2.5}$ monitor as discussed in this action.

Finally, we propose to find that the Oakridge PM_{10} maintenance plan's MVEBs meet applicable CAA requirements for maintenance plans and transportation conformity requirements. With this action, we are starting the adequacy process for these proposed MVEBs and opening a public comment period.

We note that the January 13, 2022 submittal also includes the Oakridge $PM_{2.5}$ redesignation and maintenance plan, revisions to the Lane County Code, and additional revisions to LRAPA's Title 29 rules, which EPA will address in a separate action.

V. Incorporation by Reference

In this document, EPA proposes to include in a final rule, regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA proposes to incorporate by reference the provisions described in section IV of this preamble. EPA is also proposing to remove regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA proposes to remove the City of Oakridge Ordinance 815, state effective August 15, 1996, from the incorporation by reference as described in section IV of this preamble. EPA has made, and will continue to make, these documents generally available through

[30] *See* 40 CFR 93.118.

[31] *See* EPA memorandum titled, ''EPA Region 10 Adequacy Review of Motor Vehicle Emissions Budgets in Oakridge PM_{10} Maintenance Plan'', dated April 6, 2022.

[32] On January 13, 2022, Oregon also submitted LRAPA Title 29 Sections 0020, 0050–0090, 0300 and 0320. Oregon made no changes to these sections, except for the State effective date. EPA has reviewed these rules and approved them in a previous action (83 FR 50274, March 23, 2018).

https://www.regulations.gov and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Orders Review

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submittal that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submittals, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely proposes to approve a State plan as meeting Federal requirements and does not impose additional requirements beyond those already imposed by State law. For that reason, this proposed 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 CAA; 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).

In addition, 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, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, 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.

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

Dated: April 25, 2022.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2022–09254 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

SURFACE TRANSPORTATION BOARD

49 CFR Part 1249

[Docket No. EP 769]

Uniform Railroad Costing System (URCS) Data Reporting

AGENCY: Surface Transportation Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Surface Transportation Board proposes a rule to codify a longstanding voluntary practice whereby Class I carriers, through the Association of American Railroads (AAR), have annually reported tare weight and loss and damage data for use in the Board's Uniform Railroad Costing System. Under the Board's proposal, Class I carriers may choose whether to provide tare weight and loss and damage data through AAR or file the data individually.

DATES: Comments are due by June 13, 2022. Reply comments are due by June 28, 2022.

ADDRESSES: Comments and replies may be filed with the Board via e-filing. Written comments and replies will be posted to the Board's website at *www.stb.gov.*

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245–0333. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board is authorized, under 49 U.S.C. 11161, to maintain cost accounting rules for rail carriers. In 1989, the Board's predecessor, the Interstate Commerce Commission, adopted the Uniform Railroad Costing System (URCS) as its general purpose costing system. *Adoption of the Unif. R.R. Costing Sys. as a Gen. Purpose Costing Sys. for All Regul. Costing Purposes,* 5 I.C.C.2d 894 (1989), 54 FR 38910 (September 21, 1989). The Board uses URCS for a variety of regulatory functions. URCS is used in rate reasonableness proceedings as part of the initial market dominance determination, and at later stages is used in parts of the Board's determination as to whether the challenged rate is reasonable, and, when warranted, the maximum rate prescription. URCS is also used to, among other things, develop variable costs for making cost determinations in abandonment proceedings, to provide the railroad industry and shippers with a standardized costing model, to cost the Board's Carload Waybill Sample to develop industry cost information, and to provide interested parties with basic cost information regarding railroad industry operations.

As a longstanding practice, the Association of American Railroads (AAR) has collected from Class I carriers, and voluntarily provided annually to the Board, tare weight and loss and damage data for use in URCS. While the Board appreciates AAR's longstanding voluntary practice, to ensure the continued availability of the data, which are essential components of URCS,[1] the Board proposes to formalize that reporting requirement and require Class I carriers to provide tare weight

[1] Tare weights are used in URCS to calculate gross ton-mile costs, while loss and damage data are used to calculate the total variable shipment costs of each rail movement. The Railroad Cost Program User Manual is available on the Board's website at *www.stb.gov/reports-data/uniform-rail-costing-system/.*

and loss and damage data on an annual basis, as described below. The Board has the statutory authority to obtain data from carriers and associations under 49 U.S.C. 11144 and 11145.

The Board's proposal is consistent with Class I carriers' current and longstanding practice of providing summarized tare weight and loss and damage data to the Board through AAR. AAR's practice has been to provide the average tare weight by AAR car type code [2] in tons and pounds, as well as the number of cars. Additionally, AAR has historically provided summarized annual loss and damage expenses [3] and the number of tons originated by commodity. Class I carriers are required to report, quarterly and annually, the number of tons originated on their rail lines by commodity through the freight commodity statistics (FCS) report. 49 CFR 1248.2. AAR's practice has been to provide the Board with its own version of the FCS report that aggregates data from the Class I carriers. AAR has also provided the loss and damage per ton, which is calculated by dividing loss and damage expenses by the number of tons originated by commodity. The Board proposes that Class I carriers may continue to provide tare weight and loss and damage data in this format.

The Board proposes, as an alternative for Class I carriers, to allow those carriers to individually report tare weight and loss and damage data directly to the Board. Under this option, Class I carriers would provide the tare weight totals by AAR car type code in tons and pounds and the number of cars, and the Board would calculate the average tare weight. For loss and damage data, Class I carriers would provide their total annual loss and damage expenses, number of tons originated, and loss and damage per ton by commodity using the specific commodity groupings identified in the Annual Report of Loss and Damage Data (*see* App. C), and the Board would consolidate the data to calculate the loss and damage per ton for all Class I carriers.

To ensure the timely availability of data for use in URCS, the Board proposes to require Class I carriers, either individually or through AAR, to file the annual tare weight and loss and damage data with the Board within 60 days after the end of each calendar year. Additionally, to facilitate the prompt receipt of 2021 data for use in URCS this year, the Board proposes to require Class I carriers, either individually or through AAR, to file tare weight and loss and damage data for the year 2021 within 30 days of the effective date of the final rule. To provide additional guidance, the Board proposes sample forms in Appendices B (for reporting through AAR) and C (for reporting individually) that Class I carriers may use to file tare weight and loss and damage data. The Board's Office of Economics (OE) would make technical changes to the format of these forms in the future as necessary.[4]

The Board invites comments on the proposed rule. Comments will be due by June 13, 2022; replies will be due by June 28, 2022.

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, generally requires a description and analysis of new rules that would have a significant economic impact on a substantial number of small entities. In drafting a rule, an agency is required to: (1) Assess the effect that its regulation will have on small entities, (2) analyze effective alternatives that may minimize a regulation's impact, and (3) make the analysis available for public comment. Sections 601–604. In its notice of proposed rulemaking, the agency must either include an initial regulatory flexibility analysis, section 603(a), or certify that the proposed rule would not have a ''significant impact on a substantial number of small entities,'' section 605(b). Because the goal of the RFA is to reduce the cost to small entities of complying with Federal regulations, the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates those entities. In other words, the impact must be a direct impact on small entities ''whose conduct is circumscribed or mandated'' by the proposed rule. *White Eagle Coop.* v. *Conner,* 553 F.3d 467, 480 (7th Cir. 2009).

The proposed rule would not have a significant impact on a substantial number of small entities within the meaning of the RFA [5] because it is limited to Class I carriers. Accordingly, the Board 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 as defined by the RFA. A copy of this decision will be served upon the Chief Counsel for Advocacy, Office of Advocacy, U.S. Small Business Administration, Washington, DC 20416.

Paperwork Reduction Act. Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521, Office of Management and Budget (OMB) regulations at 5 CFR 1320.8(d), and Appendix C, the Board seeks comment about the impact of the new collection for URCS Data Reporting (OMB Control No. 2140–XXXX), concerning: (1) Whether the proposed collection of information, which is further described in the proposed rule below, is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility; (2) the accuracy of the Board's burden estimates; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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, when appropriate.

The Board estimates that the proposed new requirements would include a total annual hourly burden of 28 hours and a one-time, start-up hourly burden of 63 hours. There are no non-hourly burdens associated with this collection. The Board welcomes comment on the estimates of actual time and costs of the collection, as detailed in Appendix C below. Other information pertinent to this collection is also included in

[2] AAR car type codes include freight car types and intermodal equipment:

A—Equipped box car, B—Unequipped box car, C—Covered hopper car, D—Locomotive, E—Equipped gondola, F—Flat car, G—Unequipped gondola, H—Unequipped hopper, J—Gondola car, K—Equipped hopper car, L—Special type car, M—Maintenance of way, scale, passenger, caboose, and end-of-train information systems, P—Conventional intermodal car, Q—Lighter weight, low-profile intermodal car, R—Refrigerator car, S—tack car, T—Tank car, U—Container, V—Vehicular flat car, Z—Trailer.

[3] Historically, AAR has not reported loss and damage expenses for Grand Trunk Corporation (including U.S. affiliates of Canadian National Railway Company) (CN) and Soo Line Corporation (including U.S. affiliates of Canadian Pacific Railway Company) (CP). As discussed, the Board's proposed rule would require reporting from all Class I carriers either individually or through AAR. The Board's collection of loss and damage expenses from CN and CP for inclusion in URCS, which uses industry-wide loss and damage information, would allow the Board to provide more accurate cost estimates.

[4] OE would post the revised templates to the Board's website and so notify the Class I carriers.

[5] For purposes of the RFA analysis, the Board defines a small entity as only including those rail carriers classified as Class III carriers under 49 CFR part 1201, General Instruction 1–1. *See Small Entity Size Standards Under the Regul. Flexibility Act,* EP 719 (STB served June 30, 2016), 81 FR 42566 (June 30, 2016) (with Board Member Begeman dissenting). Class III carriers have annual operating revenues of $20 million or less in 1991 dollars ($40,400,000 when adjusted for inflation using 2020 data). Class II carriers have annual operating revenues of less than $250 million in 1991 dollars ($900 million when adjusted for inflation using 2020 data). The Board calculates the revenue deflator factor annually and publishes the railroad revenue thresholds on its website. 49 CFR part 1201, General Instruction 1–1; *Indexing the Ann. Operating Revenues of R.Rs.,* EP 748 (STB served July 12, 2021), 86 FR 36590 (July 12, 2021).

Appendix C. The proposed rule will be submitted to OMB for review as required under 44 U.S.C. 3507(d) and 5 CFR 1320.11. Comments received by the Board regarding the information collection will also be forwarded to OMB for its review when the final rule is published.

List of Subjects in 49 CFR Part 1249

Railroads, Reporting and recordkeeping requirements.

It is ordered:

1. The Board requests comments on the proposed rule as set forth in this decision. Comments on are due by June 13, 2022; replies are due by June 28, 2022.

2. Notice of the proposed rule will be published in the **Federal Register**.

3. A copy of this decision will be served upon the Chief Counsel for Advocacy, Office of Advocacy, U.S. Small Business Administration.

4. This decision is effective on its service date.

Decided: April 29, 2022.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Regena Smith-Bernard,

Clearance Clerk.

■ For the reasons set forth in the preamble, the Surface Transportation Board proposes to amend title 49, chapter X, subchapter C, of the Code of Federal Regulations by adding part 1249 to read as follows:

PART 1249—REPORTS OF TARE WEIGHT AND LOSS AND DAMAGE DATA

Sec.

Authority: 49 U.S.C. 1321, 11144, 11145.

§ 1249.1 Annual Report of Tare Weight Data.

Class I carriers, either individually or through the Association of American Railroads (AAR), shall annually file tare weight data, as detailed in the Annual Report of Tare Weight Data, with the Surface Transportation Board's Office of Economics within 60 days after the end of the calendar year. Forms and instructions are available at *www.stb.gov* and may also be obtained by contacting the Office of Economics.

§ 1249.2 Annual Report of Loss and Damage Data.

Class I carriers, either individually or through AAR, shall annually file loss and damage data, as detailed in the Annual Report of Loss and Damage Data, with the Surface Transportation Board's Office of Economics within 60 days after the end of the calendar year. Forms and instructions are available at *www.stb.gov* and may also be obtained by contacting the Office of Economics.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A

Sample Forms for AAR Reporting

Annual Report of Loss And Damage Data Instructions

This report is applicable to all Class I railroads.

1. Update current reporting year.

2. For each standard transportation commodity code (STCC) identified, report total annual loss and damage expenses, the number of tons originated, and the loss and damage per ton.

3. Report the number of tons originated for each commodity for all railroads.

4. The loss and damage per ton is calculated by dividing loss and damage expenses by the number of tons originated by commodity. Round to the thousandths place.

5. For Commodity 49 Hazmat, only report data in the loss and damage column.

BILLING CODE 3510–22–P

SURFACE TRANSPORTATION BOARD

ANNUAL REPORT OF LOSS AND DAMAGE DATA

All Class I Railroads

For the year ending December 31, 20__

STCC	Commodity	Loss & Damage	Number of Tons Originated	Loss & Damage Per Ton
01	**FARM PRODUCTS**			
	0113 Grains			
	01195 Potatoes			
	012 Fresh Fruits/Tree Nuts			
	013 Fresh Vegetables			
10	**METALLIC ORES**			
11	**COAL**			
14	**NONMETALLIC MINERALS**			
20	**FOOD & KINDRED PRODUCTS**			
	2011 Fresh Meat			
	202 Dairy Products			
	203 Canned/Preserved Fruits/Vegetable			
	204 Grain Mill Products			
	2041 Flour			
	2042 Prep/Canned Animal Feeds			
	2043 Cereal Preparations			
	2044 Milled Rice/Flour/Meal			
	2045 Prepared Flour			
	2046 Corn Milling Products			
	2062 Sugar, Refined			
	20821 Beer/Ale/Porter/Stout			
	2084 Wines/Brandy/Brandy Spirits			
	20851 Distilled/Blended Liquors			
	209 Misc. Food Preparations			
21	**TOBACCO PRODUCTS**			
24	**LUMBER & WOOD PRODUCTS**			
	2421 Lumber/Dimension Stock			
	2432 Veneer/Plywood			
25	**FURNITURE & FIXTURES**			
26	**PULP/PAPER/ALLIED PRODUCTS**			
	26211 Newsprint			
	26213 Printing Paper			
	263 Paperboard/Pulpboard/Fiberboard			
	264 Conv. Paper/Paperboard Products			

	26471 Sanitary Tissues/Health Products			
28	CHEMICALS & ALLIED PRODUCTS			
	281 Industrial Chemicals			
	2812 Sodium/Potassium			
	282 Plastic Materials/Synthetic Resins			
	289 Miscellaneous Chemical Products			
29	PETROLEUM & COAL PRODUCTS			
30	RUBBER & MISC. PLASTICS			
	301 Tires/Inner Tubes			
32	STONE/CLAY/GLASS/CONC. PROD.			
	321 Flat Glass			
	3295 Nonmetallic Minerals/Earths			
33	PRIMARY METAL PRODUCTS			
	3312 Primary Iron/Steel Products			
	3352 Aluminum/ABA Basic Shapes			
34	FABRICATED METAL PRODUCTS			
	344 Fabric. Structural Metal Products			
35	MACHINERY, EXCEPT ELECTRIC			
	351 Engines/Turbines			
	352 Farm Machinery/Equipment			
	353 Constr./Mining/Material Handling			
36	ELECTRIC MACH./EQUIP/SUPPLIES			
	361 Electrical Trans./Distr. Equipment			
	363 Household Appliances			
	365 Radio/TV Sets			
37	TRANSPORTATION EQUIPMENT			
	37111 Automobiles			
	37112 Truck Tractors/Trucks			
	3714 Motor Vehicle Parts/Access.			
44	FREIGHT FORWARDER TRAFFIC			
45	SHIPPER ASSN. TRAFFIC			
46	MISC. MIXED SHIPMENTS			
	461 Miscellaneous Mixed Shipments			
	ALL OTHERS			
49	HAZMAT		†	–

† Do not report tons for Commodity 49 Hazmat.

Annual Report of Tare Weight Data Instructions

1. For each four-digit AAR Car Type Code, report the average tare weight for all Class I railroads by tons and pounds, and the number of cars.

2. Report detailed data for freight car types and intermodal equipment codes: A, B, C, D, E, F, G, H, J, K, L, M, P, Q, R, S, T, U, V, and Z.

SURFACE TRANSPORTATION BOARD

ANNUAL REPORT OF TARE WEIGHT DATA

All Class I Railroads

For the year ending December 31, 20__

AAR Car Type Code	Average Tare Weight (Tons)	Cars	Average Tare Weight (Pounds)

Appendix B

Sample Forms for Individual Reporting

Annual Report of Loss And Damage Data Instructions

This report is applicable to all Class I railroads.

1. Update current reporting year.
2. For each standard transportation commodity code (STCC) identified, report total annual loss and damage expenses, the number of tons originated, and the loss and damage per ton.
3. Report the number of tons originated for each commodity for all railroads.
4. The loss and damage per ton is calculated by dividing loss and damage expenses by the number of tons originated by commodity. Round to the thousandths place.
5. For Commodity 49 Hazmat, only report data in the loss and damage column.

SURFACE TRANSPORTATION BOARD

ANNUAL REPORT OF LOSS AND DAMAGE DATA

Railroad: _____

For the year ending December 31, 20__

STCC	Commodity	Loss & Damage	Number of Tons Originated	Loss & Damage Per Ton
01	FARM PRODUCTS			
	0113 Grains			
	01195 Potatoes			
	012 Fresh Fruits/Tree Nuts			
	013 Fresh Vegetables			
10	METALLIC ORES			
11	COAL			
14	NONMETALLIC MINERALS			
20	FOOD & KINDRED PRODUCTS			
	2011 Fresh Meat			
	202 Dairy Products			
	203 Canned/Preserved Fruits/Vegetable			
	204 Grain Mill Products			
	2041 Flour			
	2042 Prep/Canned Animal Feeds			
	2043 Cereal Preparations			
	2044 Milled Rice/Flour/Meal			
	2045 Prepared Flour			
	2046 Corn Milling Products			
	2062 Sugar, Refined			
	20821 Beer/Ale/Porter/Stout			
	2084 Wines/Brandy/Brandy Spirits			
	20851 Distilled/Blended Liquors			
	209 Misc. Food Preparations			
21	TOBACCO PRODUCTS			
24	LUMBER & WOOD PRODUCTS			
	2421 Lumber/Dimension Stock			
	2432 Veneer/Plywood			
25	FURNITURE & FIXTURES			
26	PULP/PAPER/ALLIED PRODUCTS			
	26211 Newsprint			
	26213 Printing Paper			
	263 Paperboard/Pulpboard/Fiberboard			
	264 Conv. Paper/Paperboard Products			
	26471 Sanitary Tissues/Health Products			
28	CHEMICALS & ALLIED PRODUCTS			

	281 Industrial Chemicals			
	2812 Sodium/Potassium			
	282 Plastic Materials/Synthetic Resins			
	289 Miscellaneous Chemical Products			
29	PETROLEUM & COAL PRODUCTS			
30	RUBBER & MISC. PLASTICS			
	301 Tires/Inner Tubes			
32	STONE/CLAY/GLASS/CONC. PROD.			
	321 Flat Glass			
	3295 Nonmetallic Minerals/Earths			
33	PRIMARY METAL PRODUCTS			
	3312 Primary Iron/Steel Products			
	3352 Aluminum/ABA Basic Shapes			
34	FABRICATED METAL PRODUCTS			
	344 Fabric. Structural Metal Products			
35	MACHINERY, EXCEPT ELECTRIC			
	351 Engines/Turbines			
	352 Farm Machinery/Equipment			
	353 Constr./Mining/Material Handling			
36	ELECTRIC MACH./EQUIP/SUPPLIES			
	361 Electrical Trans./Distr. Equipment			
	363 Household Appliances			
	365 Radio/TV Sets			
37	TRANSPORTATION EQUIPMENT			
	37111 Automobiles			
	37112 Truck Tractors/Trucks			
	3714 Motor Vehicle Parts/Access.			
44	FREIGHT FORWARDER TRAFFIC			
45	SHIPPER ASSN. TRAFFIC			
46	MISC. MIXED SHIPMENTS			
	461 Miscellaneous Mixed Shipments			
	ALL OTHERS			
49	HAZMAT		†	–

† Do not report tons for Commodity 49 Hazmat.

Annual Report of Tare Weight Data Instructions

1. For each four-digit AAR Car Type Code, report the total tare weight in tons and pounds, and the number of cars.

2. Report detailed data for freight car types and intermodal equipment codes: A, B, C, D, E, F, G, H, J, K, L, M, P, Q, R, S, T, U, V, and Z.

SURFACE TRANSPORTATION BOARD

ANNUAL REPORT OF TARE WEIGHT DATA

Railroad: _____

For the year ending December 31, 20__

AAR Car Type Code	Total Tare Weight (Tons)	Cars	Total Tare Weight (Pounds)

BILLING CODE 3510–22–C

Appendix C

Paperwork Reduction Act Collection

Information Collection

Title: Annual Reports of Tare Weight and Loss and Damage Data.

OMB Control Number: 2140–XXXX.

STB Form Number: None.

Type of Review: New collection.

Summary: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995, the Surface Transportation Board gives notice that it is requesting from the Office of Management and Budget approval of a new collection, Annual Reports of Tare Weight and Loss and Damage Data, OMB Control No. 2140–XXXX. The new collection is necessitated by the notice of proposed rulemaking, which proposes to give Class I carriers the option to provide tare weight and loss and damage data to the Board individually.

Respondents: Class I railroads.

Number of Respondents: Seven.

Estimated Time per Response: Four hours, plus a one-time addition of nine start-up hours.

Frequency: Annual.

Total Annual Hour Burden: 49 hours (including the additional 21 hours, which is the estimated 63 start-up hours amortized over the three-year approval period).

Total ''Non-hour Burden'' Cost: There are no non-hourly burden costs for this collection. The collections may be filed electronically.

Needs and Uses: This collection will be used by the Board in the Uniform Railroad Costing System (URCS). The Board is authorized, under 49 U.S.C. 11161, to maintain cost accounting rules for rail carriers. In 1989, the Board's predecessor, the Interstate Commerce Commission, adopted URCS as its general purpose costing system. *Adoption of the Unif. R.R. Costing Sys. as a Gen. Purpose Costing Sys. for All Regul. Costing Purposes,* 5 I.C.C.2d 894 (1989). The Board uses URCS for a variety of regulatory functions. URCS is used in rate reasonableness proceedings as part of the initial market dominance determination, and at later stages is used in parts of the Board's determination as to whether the challenged rate is reasonable and, when warranted, the maximum rate prescription. URCS is also used to, among other things, develop variable costs for making cost determinations in abandonment proceedings, to provide the railroad industry and shippers with a standardized costing model, to cost the Board's Carload Waybill Sample to develop industry cost information, and to provide interested parties with basic cost information regarding railroad industry operations.

[FR Doc. 2022–09571 Filed 5–6–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 220503–0110; RTID 0648–XB877]

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications; 2022–2023 Annual Specifications and Management Measures for Pacific Sardine

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement annual harvest specifications and management measures for the northern subpopulation of Pacific sardine (hereafter, Pacific sardine), for the fishing year from July 1, 2022, through June 30, 2023. The proposed action would prohibit most directed commercial fishing for Pacific sardine off the coasts of Washington, Oregon, and California. Pacific sardine harvest would be allowed only for use as live bait, in minor directed fisheries, as incidental catch in other fisheries, or as authorized under exempted fishing permits. The incidental harvest of Pacific sardine would be limited to 20 percent by weight of all fish per trip when caught with other stocks managed under the Coastal Pelagic Species Fishery Management Plan, or up to 2 metric tons per trip when caught with non-Coastal Pelagic Species stocks. The proposed annual catch limit for the 2022–2023 Pacific sardine fishing year is 4,274 metric tons. This proposed rule is intended to conserve, manage, and rebuild the Pacific sardine stock off the U.S. West Coast.

DATES: Comments must be received by May 24, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2022–0046, by the following method:

- *Electronic Submissions:* Submit all public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2022–0046 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method or received after the end of the comment period may not be considered by NMFS. All comments

received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Taylor Debevec, West Coast Region, NMFS, (562) 619–2052, *Taylor.Debevec@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Pacific sardine fishery in the U.S. exclusive economic zone (EEZ) off the Pacific coast (California, Oregon, and Washington) in accordance with the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The CPS FMP and its implementing regulations require NMFS to set annual catch levels for the Pacific sardine fishery based on the annual specification framework and control rules in the FMP. These control rules include the harvest guideline (HG) control rule, which, in conjunction with the overfishing limit (OFL) and acceptable biological catch (ABC) rules in the FMP, are used to manage harvest levels for Pacific sardine, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (MSA), 16 U.S.C. 1801 *et seq.*

During public meetings each year, the NMFS Southwest Fisheries Science Center (SWFSC) presents the estimated biomass for Pacific sardine to the Pacific Fishery Management Council (Council), including the Council's CPS Management Team (Team), CPS Advisory Subpanel (Subpanel), and Scientific and Statistical Committee (SSC). The Team, Subpanel, and SSC review the biomass and the status of the fishery, and recommend applicable catch limits and additional management measures. Following Council review and public comment, the Council adopts a biomass estimate and recommends catch limits and any in-season accountability measures to NMFS. NMFS publishes annual specifications in the **Federal Register** to establish these catch limits and management measures for each Pacific sardine fishing year. This rule proposes the Council's recommended catch limits for the July 1, 2022—June 30, 2023 fishing year, as well as management measures to ensure that harvest does not exceed those limits and the adoption of an OFL and ABC that take into consideration uncertainty surrounding the current estimate of biomass for Pacific sardine.

Recommended Catch Limits

According to the CPS FMP, the catch limit for the primary directed fishery is determined using the FMP-specified HG formula. This Pacific sardine HG control rule, the primary mechanism for setting the primary directed fishery catch limit, includes a CUTOFF parameter, which has been set at a biomass level of 150,000 mt. This amount is subtracted from the annual biomass estimate before calculating the applicable HG for the fishing year. Because this year's biomass estimate, 27,369 metric tons (mt), is below that value, the formula results in an HG of zero, and no Pacific sardine are available for the primary directed fishery during the 2022–2023 fishing season. This is the eighth consecutive year that the primary directed fishery is closed.

During the 2019–2020 fishing year, the estimated biomass of Pacific sardine dropped below its 50,000-mt minimum stock size threshold (MSST), which triggered an overfished determination process. Accordingly, NMFS declared the stock overfished on June 26, 2019, and notified the Council on July 9, 2019. NMFS worked with the Council to develop a rebuilding plan for Pacific sardine to implement within two years of the date and finalized it June 24, 2021 (86 FR 33142). The rebuilding plan (Amendment 18 to the CPS FMP) stipulates that total catch limits (*i.e.,* OFL/ABC/ACL) are to be set annually based on annual stock assessments, the control rules in the FMP, and recommendations from the SSC regarding uncertainty in the assessment and OFL. The rebuilding plan also includes the following management measures: (1) Closing the primary directed fishery until the biomass reaches or exceeds 150,000 mt; (2) restricting incidental limits in other primary directed CPS fisheries to no more than 20 percent until the biomass reaches or exceeds 50,000 mt; (3) limiting catch in the minor directed fishery to 1 mt per trip per day; and (4) other management measure the Council may recommend. The 2022–2023 proposed harvest specifications are consistent with the management strategy in the rebuilding plan.

At the Council's April 2022 meeting, the Council's SSC reviewed the SWFSC 2022–2023 Pacific sardine stock assessment ''Update assessment of the Pacific sardine resource in 2022 for U.S. management in 2022–2023.'' The SWFSC completes annual assessments for Pacific sardine. The type of assessment alternates between benchmark assessments in one year and update assessments the following two years. Both types of assessments are based largely on data collected from annual research cruises. The SSC agreed that the SWFSC's 2022–2023 assessment satisfied the Terms of Reference for an update assessment and that it represents the best scientific information available for management of Pacific sardine.

Based on this year's biomass estimate and the harvest control rule in the FMP, the Council recommended, and NMFS is proposing for the 2022–2023 fishing year, an OFL of 5,506 mt, an ABC of 4,274 mt, an annual catch limit (ACL) of 4,274 mt, and a prohibition on commercial Pacific sardine catch, unless it is harvested as part of the live bait, tribal,[1] or minor directed fisheries, as incidental catch in other fisheries, or as part of exempted fishing permit (EFP) activities. The Council also recommended an annual catch target (ACT) of 3,800 mt for the 2022–2023 fishing year. For comparison, the ABC/ACL and ACT adopted last year were 3,329 mt and 3,000 mt, respectively. Although the biomass estimates in 2021and 2022 are similar (28,276 mt and 27,369 mt, respectively), the proposed ABC/ACL and ACT for the 2022–2023 fishing year are higher due to the SSC's determination that there is less uncertainty associated with this year's biomass estimate compared to last year, resulting in a decrease in the scientific uncertainty buffer between the OFL and ABC.

In conjunction with setting an ACT, the Council also recommended inseason and other management measures to ensure harvest opportunity under the ACT throughout the year, which are discussed in the next section.

Recommended Management Measures

The proposed annual harvest limits and management measures were developed in the context of NMFS' July 2019 declaration that the Pacific sardine stock was overfished and June 2021 approval of a rebuilding plan for the stock. Because the biomass remains below the 50,000 mt MSST, the FMP requires that incidental catch of Pacific sardine in other CPS fisheries be limited to an incidental allowance of no more than 20 percent by weight (instead of a maximum of 40 percent allowed when below the CUTOFF but above the MSST).

The following are the proposed management measures and inseason

[1] For the 2022–2023 fishing year, the Quinault Indian Nation has not requested a tribal set-aside, and therefore none is proposed.

accountability measures for the Pacific sardine 2022–2023 fishing year:

(1) If landings in the live bait fishery reach 2,500 mt, of Pacific sardine, then a 1-mt per-trip limit of sardine would apply to the live bait fishery.

(2) An incidental per-landing limit of 20-percent (by weight) Pacific sardine applies to other CPS primary directed fisheries (*e.g.,* Pacific mackerel).

(3) If the ACT of 3,800 mt is attained, then a 1-mt per-trip limit of Pacific sardine would apply to all CPS fisheries (*i.e.,* (1) and (2) would no longer apply).

(4) An incidental per-landing allowance of 2 mt of Pacific sardine would apply to non-CPS fisheries until the ACL is reached.

At the April 2022 meeting, the Council also recommended NMFS approve three EFP proposals requesting an exemption from the prohibition to directly harvest sardine during their discussion of sardine management measures. Those EFP proposals include a total amount of up to 830 mt of the ACL.

All sources of catch including any fishing occurring as part of an EFP, the live bait fishery, and other minimal sources of harvest, such as incidental catch in CPS and non-CPS fisheries, and minor directed fishing, will be accounted for against the ACT and ACL.

The NMFS West Coast Regional Administrator would publish a notice in the **Federal Register** to announce when catch reaches the incidental limits, as well as any changes to allowable incidental catch percentages. Additionally, to ensure that the regulated community is informed of any closure, NMFS would make announcements through other means available, including emails to fishermen, processors, and state fishery management agencies.

This action must be effective by July 1, 2022; otherwise the fishery will open without any catch limits or restrictions in place. In order to ensure that these harvest specifications are effective in time for the start of the July 1 fishing year, NMFS will solicit public comments on this proposed rule for 15 days rather than the standard 30 days. A 15-day comment period has been the practice since the 2015–2016 fishing year, when the primary directed fishery for sardine was first closed. NMFS received the recommendations from the Council that form the basis for this rule only last month. The subject of this proposed rule—the establishment of the reference points—is considered a routine action, because they are calculated annually based on the framework control rules in the FMP. Additionally, the Council provided an opportunity for public comment at its April 2022 meeting, as it does every year before adopting the recommended harvest specifications and management measures for the proceeding fishing year.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the CPS FMP, other provisions of the MSA, and other applicable law, subject to further consideration after public comment.

This proposed rule is exempt from review under Executive Order 12866.

Pursuant to Executive Order 13175, this proposed rule was developed after meaningful consultation and collaboration with the tribal representative on the Council who has agreed with the provisions that apply to tribal vessels.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the following reasons:

For Regulatory Flexibility Act (RFA) purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

The purpose of this proposed rule is to conserve and rebuild the Pacific sardine stock by preventing overfishing, while still allowing harvest opportunity among differing fishery sectors. This will be accomplished by implementing the 2022–2023 annual specifications for Pacific sardine in the U.S. EEZ off the West coast. The small entities that would be affected by the proposed action are the vessels that would be expected to harvest Pacific sardine as part of the West Coast CPS small purse seine fleet. In 2014, the last year that a directed fishery for Pacific sardine was allowed, there were approximately 81 vessels permitted to operate in the directed sardine fishery component of the CPS fishery off the U.S. West Coast; 58 vessels in the Federal CPS limited entry fishery off California (south of 39° N. lat.); and a combined 23 vessels in Oregon and Washington's state Pacific sardine fisheries. We do not collect or have access to information about affiliation between vessels or affiliation between vessels and processing entities in this fishery, or receipts in Alaska, Hawaii, or international fisheries, so it is possible that some impacted entities may exceed $11 million in ex-vessel revenue or another size-standard threshold. Based on available data, the average annual west coast revenue per vessel for all west coast vessels, including those described above potentially affected by this rule, was well below the threshold level of $11 million as of 2022; therefore, all of these vessels are considered small businesses under the RFA. Because each affected vessel is a small business, this proposed rule is considered to equally affect all of these small entities in the same manner. Therefore, this rulemaking would not create disproportionate costs between small and large vessels/businesses.

The CPS FMP and its implementing regulations require NMFS to annually set an OFL, ABC, ACL, and HG or annual catch target for the Pacific sardine fishery based on the specified harvest control rules in the FMP applied to the current stock biomass estimate for that year. The derived annual HG is the level typically used to manage the principal commercial sardine fishery and is the harvest level NMFS typically uses for profitability analysis each year. As stated above, the CPS FMP dictates that when the estimated biomass drops below a certain level (150,000 metric tons (mt)), the HG is zero. Because there is again no directed fishing for the 2022–2023 fishing year, this proposed rule will not change the potential profitability compared to the previous fishing year. Additionally, the proposed 2022–2023 ACL is slightly higher compared to previous years, and is still expected to account for the various fishery sector needs (*i.e.,* live bait, incidental catch in other CPS fisheries, and minor directed fisheries).

The revenue derived from harvesting Pacific sardine is typically only one of the sources of fishing revenue for the commercial vessels that participate in this fishery. As a result, the economic impact to the fleet from the proposed action cannot be viewed in isolation. From year to year, depending on market conditions and availability of fish, most CPS/sardine vessels supplement their income by harvesting other species. Many vessels in California also harvest anchovy, mackerel, and in particular, squid, making Pacific sardine only one component of a multi-species CPS fishery. Additionally, some sardine vessels that operate off of Oregon and Washington also fish for salmon in

Alaska or squid in California during times of the year when sardine are not available. The purpose of the incidental catch limits proposed in this action are to ensure the vessels impacted by a prohibition on directly harvesting sardine can still access these other profitable fisheries while still minimizing Pacific sardine harvest.

CPS vessels typically rely on multiple species for profitability because abundance of Pacific sardine, like the other CPS stocks, is highly associated with ocean conditions and seasonality. Variability in ocean conditions and season results in variability in the timing and location of CPS harvest throughout the year. Because each species responds to ocean conditions in its own way, not all CPS stocks are likely to be abundant at the same time. Therefore, as abundance levels and markets fluctuate, the CPS fishery as a whole has relied on a group of species for its annual revenues.

Therefore the proposed action, if adopted, will not have a significant economic impact on a substantial number of small entities. As a result, an Initial Regulatory Flexibility Analysis is not required, and none has been prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the proposed action.

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

Dated: May 3, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–09926 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 89
Monday, May 9, 2022

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

Submission for OMB Review; Comment Request

May 4, 2022.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 8, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Food Program Reporting System (FPRS) forms FNS 583 and FNS 366B.

OMB Control Number: 0584–0594.

Summary of Collection: The Food and Nutrition Service (FNS) is consolidating certain programmatic and financial data reporting requirements under the Food Programs Reporting System (FPRS), an electronic reporting system. The purpose is to give State agencies and Indian Tribal Organization (ITO) agencies one portal for the various reporting required for the programs that the State and ITO agencies operate.

Need and Use of the Information: The data collected will be used for a variety of purposes, mainly program evaluation, planning, audits, funding, research, regulatory compliance and general statistics. The data is gathered at various times, ranging from monthly, quarterly, annual or final submissions. Without the information, FNS would be unable to meet its legislative and regulatory reporting requirements for the affected programs. This specific revision is solely for forms FNS 583 and FNS 366B associated with rulemaking 0584 AE68.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 12,708.

Frequency of Responses: Reporting: Quarterly, Semi-annually, Monthly; Annually.

Total Burden Hours: 102,113.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–09886 Filed 5–6–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 8, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Permanent, Privately Owned Horse Quarantine Facilities.

OMB Control Number: 0579–0313.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any such animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of Public Law 107–171, May 13, 2002, the Farm Security and Rural Investment Act of 2002 [7 U.S.C. 8301 *et seq.*).

The Animal and Plant Health Inspection Service (APHIS) regulations in subpart C of part 93, on the importation of horses include

requirements for the approval and establishment of permanent, privately owned horse quarantine facilities that are operated under APHIS supervision. These regulations necessitate the use of several information collection activities when applicants apply for approval to establish and operate permanent, privately owned quarantine facilities for horses.

Need and Use of the Information: APHIS will collect the following information to ensure that horses can be imported into the United States without compromising its ability to protect against the introduction of communicable diseases of horses: (1) Environment Certification, (2) Application for Facility Approval, (3) Service Agreements, (4) Letter Challenging Withdrawal for Facility Approval, (5) Letter Notifying APHIS of Facility Closure, (6) Memorandum of Understanding/Compliance Agreement, (7) Security Instructions, (8) Alarm Notification, (9) Security Breach, (10) List of Personnel, (11) Signed Statements, (12) Daily Log, (13) Request for Variance, (14) Authorization Access Affidavits, and (15) Standards Operating Procedures. Without the information APHIS would be unable to approve permanent, privately owned horse quarantine facilities. Importers of horses would find it difficult to get quarantine space at either Federal facilities or temporary, privately owned facilities, which could decrease equine imports. This would impede trade and create challenges for the U.S. equine industry.

Description of Respondents: Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 17.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 158.

Dated: May 4, 2022.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–09932 Filed 5–6–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Storage and Use of Explosives and Magazine Security on National Forest System Lands Under a Special Use Authorization

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments on a new information collection request entitled *Storage and Use of Explosives and Magazine Security on National Forest System Lands Under a Special Use Authorization.*

DATES: Comments must be received in writing by July 8, 2022.

ADDRESSES: Comments concerning this notice should be sent to Sean Wetterberg, National Winter Sports Program Manager, 125 South State Street, Suite 7105, Salt Lake City, UT 84138. Comments also may be submitted by email at *sean-sarek.wetterberg@usda.gov.*

The public may inspect comments received at the address above during normal business hours. Visitors are encouraged to call ahead to facilitate entry to the building at 801–975–3793.

FOR FURTHER INFORMATION CONTACT: Sean Wetterberg, National Winter Sports Program Manager at 801–975–3793 or by email at *sean-sarek.wetterberg@usda.gov.* Individuals who use telecommunication devices for the deaf may call the Federal Relay Service FRS at 800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Storage and Use of Explosives and Magazine Security on National Forest System Lands Under a Special Use Authorization.

OMB Number: 0596–0252.

Expiration: March 31, 2023.

Type of Request: Renewal without revisions of an information collection.

Abstract: The Agency requires special use authorizations involving explosives management to include clause B–29 in Forest Service Handbook 2709.11, Chapter 50, section 52.2 to improve security and administration of explosives magazines that are authorized under a special use authorization. Clause B–29 requires authorization holders to comply with applicable United States Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives, state, or Department of the Army requirements and applicable Forest Service requirements.

To allow the Forest Service to monitor holder compliance with clause B–29, the revised directives require holders of an authorization containing the clause to submit certain documentation annually as part of their operating plan. The required documentation includes copies of a log containing the date and type of magazine inspections (including inspections required every seven days) and the date all deficiencies identified in any magazine inspection report were corrected; copies of any magazine inspection reports; a copy of the holder's current ATF-issued federal explosives license or federal explosives permit, if applicable; and a copy of a log containing the date of the most recent magazine lock and key replacement.

Estimate of Annual Burden: 10 minutes.

Type of Respondents: Holders of a special use authorization authorizing the storage and use of explosives.

Estimated Annual Number of Respondents: 60.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 10 hours.

Comment Is Invited: Comment is invited on (1) whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Gordon Blum,

Director, Recreation Heritage Volunteers Resources.

[FR Doc. 2022–09881 Filed 5–6–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–21–2022]

Approval of Expansion of Subzone 196AI TTI, Inc., Fort Worth, Texas

On February 15, 2022, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by Alliance Corridor, Inc., grantee of FTZ 196, requesting expanded subzone status subject to the existing activation limit of FTZ 196, on behalf of TTI, Inc., in Fort Worth, Texas.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (87 FR 9570–9571, February 22, 2022). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to expand Subzone 196A was approved on May 4, 2022, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 196's 2,000-acre activation limit.

Dated: May 4, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–09918 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–18–2022]

Foreign-Trade Zone (FTZ) 22—Chicago, Illinois; Notification of Proposed Production Activity; AbbVie, Inc.; (Pharmaceutical Products); Chicago, Illinois

AbbVie, Inc., submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in Chicago, Illinois within Subzone 22S. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on April 29, 2022.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material and specific finished product described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz*. The proposed finished product and material would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished product is prolinamide tablets (duty-free).

The proposed foreign-status material is prolinamide active pharmaceutical ingredient (duty rate 3.7%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov*. The closing period for their receipt is June 21, 2022.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov*.

Dated: May 4, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–09876 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

[C–533–878]

Stainless Steel Flanges From India: Final Results of Countervailing Duty Administrative Review; 2019

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

SUMMARY: The Department of Commerce (Commerce) finds countervailable subsidies are being provided to producers and exporters of stainless steel flanges from India during the period of review, January 1, 2019, through December 31, 2019.

DATES: Applicable May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Rachel Greenberg or Eliza Siordia, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1110 or (202) 482–3878, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on November 4, 2021.[1] On February 7, 2022, Commerce extended the deadline for the final results of this review until May 3, 2022.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Order[4]

The merchandise covered by the *Order* is stainless steel flanges from India. For a complete description of the scope of the order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in interested parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues raised by interested parties and to which we responded in the Issues and Decision Memorandum is provided in Appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

After evaluating the comments received from interested parties and record information, we have made no changes to the net subsidy rates calculated for Chandan Steel Limited (Chandan) and Kisaan Die Tech Pvt Ltd. (Kisaan). For a discussion of these comments, *see* the Issues and Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a financial contribution from a government or public entity that gives rise to a benefit to the recipient, and the subsidy is specific.[5] For a full description of the methodology underlying our conclusions, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

For the companies not selected for individual review, because the rates calculated for Chandan and Kisaan are above *de minimis* and not based entirely on facts available, we applied a subsidy rate based on the weighted-average of

[1] *See Stainless Steel Flanges from India: Preliminary Results of Countervailing Duty Administrative Review; 2019,* 86 FR 60795 (November 4, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Stainless Steel Flanges from India: Extension of Deadline for Final Results of Countervailing Duty Administrative Review, 2019,'' dated February 7, 2022.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Stainless Steel Flanges from India; 2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Stainless Steel Flanges from India: Countervailing Duty Order,* 83 FR 50336 (October 5, 2018) (*Order*).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

the subsidy rates calculated for Chandan and Kisaan using publicly ranged sales data submitted by the respondents.[6] We have made no changes to the subsidy rate calculated for companies not selected for individual review.

Final Results of Administrative Review

In accordance with section 751(a)(1)(A) of the Act and 19 CFR 351.221(b)(5), we determine the total estimated net countervailable subsidy rates for the period January 1, 2019, through December 31, 2019, to be as follows:

Company	Subsidy rate (percent *ad valorem*)
Chandan Steel Limited	5.51
Kisaan Die Tech Pvt Ltd	5.28
Non-Selected Companies Under Review[7]	5.49

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because there are no changes from the *Preliminary Results,* there are no new calculations to disclose.

Assessment Rate

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. Commerce intends to issue appropriate assessment instructions to CBP no earlier than 35 days after publication of these final results. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts indicated above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: May 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Appendix II—List of Companies Not Selected for Individual Examination

Arien Global
Arien Metals Private Limited
Armstrong International Pvt. Ltd.
Avini Metal Limited
Balkrishna Steel Forge Pvt. Ltd.
Bebitz Flanges Works Pvt. Ltd.
Bee Gee Enterprises
BFN Forgings Private Limited
Bsl Freight Solutions Pvt., Ltd.
CD Industries (Prop. Kisaan Engineering Works Pvt. Ltd).
Cipriani Harrison Valves Pvt. Ltd.
CTL Logistics (India) Pvt. Ltd.
Dongguan Good Luck Furniture Industrial Co., Ltd.
DSV Air and Sea Pvt. Ltd.
DSV Logistics
Echjay Forgings Pvt. Ltd.
Fivebros Forgings Pvt. Ltd.
Fluid Controls Pvt. Ltd.
Geodis Oversea Pvt., Ltd.
Globelink WW India Pvt., Ltd.
Good Luck Engineering Co.
Goodluck India Ltd.
Hilton Metal Forging Limited
Jai Auto Pvt. Ltd.
Jay Jagdamba Limited
Jay Jagdamba Profile Private Limited
Jay Jagdamba Forgings Private Limited
Katariya Steel Distributors
Kunj Forgings Pvt. Ltd.
Montane Shipping Pvt., Ltd.
Noble Shipping Pvt. Ltd.
Paramount Forge
Pashupati Ispat Pvt. Ltd.
Pashupati Tradex Pvt., Ltd.
Peekay Steel Castings Pvt. Ltd.
Pradeep Metals Ltd.
R D Forge Pvt., Ltd.
Rolex Fittings India Pvt. Ltd.
Rollwell Forge Pvt. Ltd.
Safewater Lines (I) Pvt. Ltd.
Saini Flange Pvt. Ltd.
SAR Transport Systems
Shilpan Steelcast Pvt. Ltd.
Shree Jay Jagdamba Flanges Private Limited
Teamglobal Logistics Pvt. Ltd.
Technical Products
Technical Products Corporation
Technocraft Industries India Ltd.
Transworld Enterprises
Transworld Global Logistics Solutions (India) Pvt. Ltd.
Transworld Group
VEEYES Engineering Pvt. Ltd.
Viraj Profiles Ltd.
Vishal Shipping Agencies Pvt. Ltd.
Yusen Logistics (India) Pvt. Ltd.

[FR Doc. 2022–09910 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–909]

Certain Steel Nails From the People's Republic of China; 2020–2021: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2020–2021

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines

[6] *See* Memorandum, ''Calculation of Subsidy Rate for Non-Selected Companies Under Review,'' dated October 29, 2021.

[7] *See* Appendix II for a list of the companies not selected for individual examination.

that eleven companies subject to this review had no shipments of certain steel nails (nails) from the People's Republic of China (China) during the period of review (POR) August 1, 2020, through July 31, 2021. Commerce also preliminarily determines that no company subject to this review established its eligibility for a separate rate and all entries of subject merchandise during the POR will be subject to the China-wide entity rate. We invite interested parties to comment on these preliminary results.

DATES: Applicable May 9, 2022.

FOR FURTHER INFORMATION CONTACT: William Horn or Zachariah Hall, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4868 or (202) 482–6261, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 2008, Commerce published the antidumping duty order on nails from China.[1] On August 2, 2021, we published a notice of opportunity for interested parties to request that Commerce conduct an administrative review of the *Order*.[2] On August 31, 2021, Commerce received requests for an administrative review from Mid Continent Steel & Wire, Inc. (the petitioner), and from Tianjin Jinchi Metal Products Co., Ltd. (Tianjin Jinchi), Shanghai Yueda Nails Industry Co. (Shanghai Yueda), and Tianjin Jinghai County Hongli Industry & Business Co. (Tianjin Jinghai) (collectively, foreign interested parties).[3] Commerce published the initiation of this administrative review on October 7, 2021.[4] The POR is August 1, 2020, through July 31, 2021. After publication of the *Initiation Notice,* Shanghai Yueda withdrew its participation in this administrative review.[5] No company submitted a separate rate application or certification to establish its eligibility for a separate rate.

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via the Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by the *Order* are nails from China. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

Thirteen companies submitted no shipment certifications. Based on our analysis of U.S. Customs and Border Protection (CBP) information and information provided by companies subject to this review, Commerce preliminarily determines that 11 companies had no shipments of subject merchandise during the POR.[7] Additionally, two of these companies, Dezhou Hualude Hardware Products Co., Ltd. (Dezhou Hualude) and Tianjin Zhonglian Metals Ware Co., Ltd. (Tianjin Zhonglian) failed to support their claim of no shipments during the POR. For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Consistent with our practice, we are not rescinding this review with respect to these companies but, instead, intend to complete the review and issue appropriate instructions to CBP based on the final results of the review.[8]

China-Wide Entity

In accordance with Commerce's policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the China-wide entity.[9] Because no party requested a review of the China-wide entity, the China-wide entity is not under review and the weighted-average dumping margin for the China-wide entity is not subject to change (*i.e.,* 118.04 percent).[10]

Aside from the 11 companies which we preliminarily find made no shipments during the POR, Commerce considers all other companies for which a review was requested, and which did not demonstrate their separate rate eligibility to be part of the China-wide entity.[11]

Preliminary Results

Commerce finds that no company subject to this administrative review has established its eligibility for a separate rate. Because 15 companies did not submit separate rate applications or certifications, or no-shipment certifications, and two companies which submitted no-shipment certifications failed to respond to the results of our no-shipment inquiry to demonstrate they had no shipments of subject merchandise to the United States during the POR, we preliminarily determine that these 17 companies are not eligible for a separate rate and are part of the China-wide entity. *See* Appendix II of this notice.

Disclosure and Public Comment

Normally, Commerce discloses the calculations used in its analysis to parties in a review within five days of the date of publication of the notice of preliminary results, in accordance with 19 CFR 351.224(b). However, in this

[1] *See Notice of Antidumping Duty Order: Certain Steel Nails from the People's Republic of China,* 73 FR 44961 (August 1, 2008) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 41436 (August 2, 2021).

[3] *See* Petitioner's Letter, ''Certain Steel Nails from China—Request for Administrative Review,'' dated August 31, 2021, at 1–2; *see also* Foreign Interested Parties' Letter, ''*Request for Administrative Review* of the Antidumping Duty Order on Certain Steel Nails from the People's Republic of China, A–570–909 (POR 8/1/20–7/31/21),'' dated August 31, 2021, at 1–2.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 55811 (October 7, 2021) (*Initiation Notice*).

[5] *See* Shanghai Yueda's Letter, ''Shanghai Yueda Notice of Withdrawal from the Review: Thirteenth Administrative Review of the Antidumping Duty Order on Certain Steel Nails from the People's Republic of China (A–570–909),'' dated November 8, 2021.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Certain Steel Nails from the People's Republic of China; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] The companies that we preliminarily determine had no shipments during the POR are: Hebei Minmetals Co., Ltd.; Nanjing Caiqing Hardware Co., Ltd.; Nanjing Yuechang Hardware Co., Ltd.; Shandong Qingyun Hongyi Hardware Products Co., Ltd.; Shanxi Hairui Trade Co., Ltd.; Shanxi Pioneer Hardware Industrial Co., Ltd.; S-Mart (Tianjin) Technology Development Co., Ltd.; Suntec Industries Co., Ltd.; Tianjin Jinchi Metal Products Co., Ltd.; Tianjin Jinghai County Hongli Industry & Business Co., Ltd.; and Xi'an Metals & Minerals Import & Export Co., Ltd.

[8] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011).

[9] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[10] *See Order.*

[11] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.'').

case, there are no calculations on the record to disclose.

Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[12] Rebuttal briefs may be filed no later than seven days after the written comments are filed, and all rebuttal comments must be limited to comments raised in the case briefs.[13] Pursuant to 19 CFR 351.309(c)(2), parties submitting case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties wishing to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Hearing requests should contain the party's name, address, telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, parties will be notified of the date and time for the hearing to be held.[14] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[15]

Unless otherwise extended, we intend to issue the final results of this review, which will include the results of our analysis of the issues raised in any briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h).

[12] *See* 19 CFR 351.309(c).

[13] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications are in effect).'').

[14] *See* 19 CFR 351.310(d).

[15] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review, in accordance with 19 CFR 351.212(b)(1). If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 118.04 percent to all entries of subject merchandise during the POR which were exported by 17 companies in the China-wide entity. If Commerce continues to make a no-shipment finding in the final results for each of the 11 companies referenced in the ''Preliminary Determination of No Shipments'' section above, any suspended entries of subject merchandise associated with those companies will also be liquidated at the China-wide rate.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) For the companies identified above that have no shipments, the cash deposit rate will continue to be the rate previously assessed for each individual exporter of subject merchandise; (2) for previously investigated or reviewed Chinese and non-Chinese exporters of subject merchandise for which a review was not requested and that received a separate rate based on a completed prior segment of this proceeding, the cash deposit rate will continue to be that existing cash deposit rate published for the most recently completed period; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be 118.04 percent, the weighted-average dumping margin for the China-wide entity from the less-than-fair value investigation; and (4) for all non-Chinese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing the preliminary results of this administrative review in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: May 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Companies Preliminarily Determined To Be Part of the China-Wide Entity

1. Dezhou Hualude Hardware Products Co., Ltd.
2. Huanghua Jinhai Hardware Products Co., Ltd.
3. Huanghua Xionghua Hardware Products Co., Ltd.
4. Jining Dragon Fasteners Co., Ltd.
5. Jining Huarong Hardware Products Co., Ltd.
6. Jining Yonggu Metal Products Co., Ltd.
7. SDC International Australia Pty. Ltd.
8. Shandong Oriental Cherry Hardware Group Heze Products Co., Ltd.
9. Shandong Oriental Cherry Hardware Import and Export Co., Ltd.
10. Shanghai Curvet Hardware Products Co., Ltd.
11. Shanghai Yueda Nails Industry Co., Ltd., a.k.a. Shanghai Yueda Nails Co., Ltd.
12. Shanxi Tianli Industries Co., Ltd.
13. Tianjin Jishili Hardware Products Co., Ltd.
14. Tianjin Universal Machinery Imp. & Exp.

Corporation
15. Tianjin Zhitong Metal Products Co., Ltd.
16. Tianjin Zhonglian Metals Ware Co., Ltd.
17. Zhejiang Gem-Chun Hardware Accessory Co., Ltd.

[FR Doc. 2022–09927 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–839, A–583–833]

Polyester Staple Fiber From the Republic of Korea 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 polyester staple fiber (PSF) from the Republic of Korea (Korea) and Taiwan would be likely to lead to continuation or recurrence of dumping at levels identified in the ''Final Results of Sunset Reviews'' section of this notice.

DATES: Applicable May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Theodore Pearson, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2631.

SUPPLEMENTARY INFORMATION:

Background

On May 25, 2000, Commerce published the AD orders on PSF from Korea and Taiwan.[1] On January 3, 2022, Commerce published the notice of initiation of the fourth sunset reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On January 14, 2022, Commerce received timely and complete notices of intent to participate in these sunset reviews from the domestic interested parties [3] within the deadline specified in 19 CFR 351.218(d)(1)(i), after the date of publication of the *Initiation Notice.*[4] The domestic interested parties claimed interested party status under sections 771(9)(C) of the Act as manufacturers in the United States of the domestic-like product.

On February 2, 2022, the domestic interested parties filed timely and adequate substantive responses, within the deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce received no substantive responses from any respondent interested parties nor was a hearing requested.[6] As a result, pursuant to 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 *Orders.*

Scope of the Orders

The merchandise subject to the *Orders* is PSF from Korea and Taiwan. For a complete description of the scope of the *Orders, see* the Issues and Decision Memorandum.[7]

Analysis of Comments Received

A complete discussion of all issues raised in these reviews is provided in the Issues and Decision Memorandum, A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Reviews

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

Country	Weighted-average dumping margin (percent)
Korea	7.48
Taiwan	9.90

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are 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: May 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

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

[FR Doc. 2022–09912 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Polyester Staple Fiber from the Republic of Korea and Antidumping Duty Orders: Certain Polyester Staple Fiber from the Republic of Korea and Taiwan,* 65 FR 33807 (May 25, 2000) (*Orders*); *see also Certain Polyester Staple Fiber from Korea: Notice of Amended Final Determination and Amended Order Pursuant to Final Court Decision,* 68 FR 74552 (December 24, 2003) (*Korea Amended Order*).

[2] *See Initiation Notice of Five-Year (Sunset) Reviews,* 87 FR 76 (January 3, 2022) (*Initiation Notice*).

[3] The domestic interested parties are Auriga Polymers Inc. (Auriga), Fiber Industries LLC (Fiber Industries), and Nan Ya Plastics Corporation, America (Nan Ya America) (collectively, domestic interested parties).

[4] *See* Domestic Interested Parties' Letters, ''Five-Year Sunset Review of the Antidumping Order on Polyester Staple Fiber from the Republic of Korea—Notice of Intent to Participate,'' and ''Five-Year Sunset Review of the Antidumping Order on Polyester Staple Fiber from Taiwan—Notice of Intent to Participate,'' both dated January 14, 2022 (collectively, Notice of Intent to Participate).

[5] *See* Domestic Interested Parties' Letters, ''Polyester Staple Fiber from the Republic of Korea—Domestic Interested Parties Substantive Response''; and ''Polyester Staple Fiber from Taiwan—Domestic Interested Parties Substantive Response,'' both dated February 2, 2022.

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated on January 3, 2022,'' dated February 22, 2022.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Sunset Reviews of the Antidumping Duty Orders on Polyester Staple Fiber from the Republic of Korea and Taiwan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–877]

Stainless Steel Flanges From India: Final Results of Antidumping Duty Administrative Review; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) determines that exporters/producers of stainless steel flanges from India made sales of subject merchandise at prices below normal value during the period of review (POR) October 1, 2019, through September 30, 2020.

DATES: Applicable May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros or Christopher Maciuba, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7425 or (202) 482–0413, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce selected two companies, Chandan Steel Limited (Chandan) and Kisaan Die Tech Private Limited (KDT), for individual examination. On November 4, 2021, Commerce published the *Preliminary Results* and invited interested parties to comment.[1] On January 7, 2022, Chandan, Echjay Forgings Private Limited (Echjay), and the petitioner[2] submitted case briefs.[3] From January 19 to 21, 2022, KDT, the petitioner, and Chandan submitted rebuttal briefs.[4] On February 15, 2022, we extended the deadline for issuance of these final results to May 3, 2022.[5] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[6] Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the order is stainless steel flanges from India. For a complete description of the scope of this order, *see* the Issues and Decision Memorandum.[7]

Analysis of Comments Received

We addressed all issues raised in the case and rebuttal briefs in the Issues and Decision Memorandum.[8] Attached to this notice, in Appendix I, is a list of the issues which parties raised. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we made certain changes to the margin calculations for Chandan and KDT. For a discussion of these changes, *see* the Issues and Decision Memorandum.[9]

Rate for Companies Not Selected for Individual Examination

The Act and Commerce's regulations do not address the rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value (LTFV) investigation, for guidance. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

For the final results, Commerce calculated estimated weighted-average dumping margins for Chandan and KDT that are not zero, *de minimis,* or based entirely on facts otherwise available. Accordingly, Commerce has continued to calculate the rate for companies not selected for individual examination using a weighted average of the margins calculated for Chandan and KDT weighted by each respondent's publicly-ranged total U.S. sale values.[10]

Final Results of Administrative Review

The final estimated weighted-average dumping margins are listed below for the POR, October 1, 2019, through September 30, 2020:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Chandan Steel Limited	3.66
Kisaan Die Tech Private Limited	1.27
Companies Not Selected for Individual Examination[11]	3.40

Disclosure

We intend to disclose the calculations performed for the final results within five days of the publication of this

[1] *See Stainless Steel Flanges from India: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Successor-in-Interest Determination, and Partial Rescission; 2019–2020,* 86 FR 60792 (November 4, 2021) (*Preliminary Results*).

[2] The petitioner is the Coalition of American Flange Producers.

[3] *See* Chandan's Letter, ''Certain Stainless-steel Flanges from India (A–533–877–AR2): Case Brief,'' dated January 7, 2022; *see also* Echjay's Letter, ''Stainless Steel Flanges from India,'' dated January 7, 2022; and Petitioner's Letter, ''Case Brief,'' dated January 7, 2022.

[4] *See* KDT's Letter, ''KDT's Rebuttal to Petitioners Case Brief,'' dated January 19, 2022; *see also* Petitioner's Letter, ''Rebuttal Brief,'' dated January 20, 2022; and Chandan's Letter, ''Rebuttal Brief on behalf of Chandan Steel,'' dated January 21, 2022.

[5] *See* Memorandum, ''Stainless Steel Flanges from India: Extension of Deadline for Final Results of Antidumping Duty Administrative Review, 2019–2020,'' dated February 15, 2022.

[6] *See* Memorandum, ''Stainless Steel Flanges from India: Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review; 2019–2020,'' dated May 3, 2022 (Issues and Decision Memorandum) which is dated concurrently with, and hereby adopted by, this notice.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] With more than one respondent under examination, Commerce normally calculates: (A) A weighted average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged U.S. sale values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects either the (B) or (C) rate based on the rate closest to (A) as the most appropriate rate for companies not selected for individual examination. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). In this review, Commerce based the rate for companies not selected for individual examination on the publicly-ranged sales data of the mandatory respondents. For an analysis of the data, *see* Memorandum, ''Final Results of the Antidumping Duty Administrative Review of Stainless Steel Flanges from India: Calculation of Margin for Respondents Not Selected for Individual Examination,'' dated May 3, 2022.

[11] *See* Appendix II for a full list of these companies.

notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review. Pursuant to 19 CFR 351.212(b)(1), for Chandan and KDT, we calculated importer-specific *ad valorem* assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales.

For the companies which were not selected for individual examination, we will assign an assessment rate based on the methodology described in the ''Rate for Companies Not Selected for Individual Examination'' section, above.

We intend to issue appropriate assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2) of the Act: (1) The cash deposit rate for Chandan, KDT, and the companies not selected for individual examination will be the rate established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered by this review but covered in a prior segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding; (3) if the exporter is not a firm covered by this review, a previous review, or the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; (4) the case deposit rate for all other producers or exporters will continue to be 7.00 percent,[12] the all-others rate established in the LTFV investigation. These cash deposits, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: May 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

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

Appendix II—List of Companies Not Selected for Individual Examination

Ae Engineers & Exporters
Balkrishna Steel Forge Pvt. Ltd.
BFN Forgings Private Limited (former name Bebitz Flanges Works Private Limited) [13]
Broadway Overseas Ltd.
Dongguan Good Luck Furniture Industrial Co., Ltd.
DSV Air and Sea Pvt. Ltd.
DSV Logistics
G.I. Auto Pvt. Ltd.
Jai Auto Pvt. Ltd.
Jay Jagdamba Forgings Private Limited
Jay Jagdamba Limited [14]
Jay Jagdamba Profile Private Limited
Katariya Steel Distributors
Lotus CNC Components
Motor Aids
Shree Jay Jagdamba Flanges Private Limited
Transworld Enterprises
Transworld Group
Viraj Profiles Ltd.

[FR Doc. 2022–09911 Filed 5–6–22; 8:45 am]

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[12] *See Stainless Steel Flanges from India: Notice of Court Decision Not in Harmony with the Final Determination of Antidumping Investigation; Notice of Amended Final Determination,* 86 FR 50325 (August 30, 2021).

[13] We find that BFN Forgings Private Limited is the successor-in-interest to Bebitz Flanges Works Private Limited. *See* IDM. This determination is unchanged from the *Preliminary Results. See Preliminary Results* PDM at ''Preliminary Successor-In-Interest Determination'' for full discussion.

[14] We also initiated a review of this company under the name ''Jay Jagdamba Ltd.'' We are treating these companies as the same entity for purposes of this segment of the proceeding.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–884]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Final Results of Countervailing Duty Administrative Review; 2019

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

SUMMARY: The Department of Commerce (Commerce) determines that producers/exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea) received countervailable subsidies during the period of review (POR) January 1, 2019, through December 31, 2019.

DATES: Applicable May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this review on November 4, 2021.[1] On December 21, 2021, Commerce issued a post-preliminary analysis relating to two programs.[2] On February 25, 2022, Commerce extended the deadline for the final results of this administrative review until May 3, 2022.[3] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4]

Scope of the Order

The product covered by this order is hot-rolled steel. For a complete description of the scope of this order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

We addressed all issues raised in interested parties' case briefs in the Issues and Decision Memorandum accompanying this notice. A list of the issues raised by parties, to which Commerce responded in the Issues and Decision Memorandum, is provided as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

After evaluating the comments received from interested parties and record information, we have made certain changes to our analysis, but have made no changes to the net subsidy rate calculated for Hyundai Steel. For a discussion of these comments, *see* the Issues and Decision Memorandum.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a description of the methodology underlying Commerce's conclusions, *see* the Issues and Decision Memorandum.

Final Rate for Non-Selected Company Under Review

There is one company in this review that was not selected as a mandatory respondent, *i.e.,* POSCO. Because the subsidy rate calculated for mandatory respondent Hyundai Steel was above *de minimis* and not based entirely on facts available, we are applying that rate to POSCO. This methodology for establishing the subsidy rate for the non-selected company is consistent with our practice and with section 705(c)(5)(A) of the Act.

Final Results of Administrative Review

We determine that, for the period January 1, 2019, through December 31, 2019, the following net countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
Hyundai Steel Company[6]	0.56
POSCO	0.56

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because there are no changes from the *Preliminary Results* and Post-Preliminary Analysis, there are no new calculations to disclose.

Assessment Rate

Pursuant to section 751(a)(2)(C), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the companies listed above. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

[1] *See Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review and Rescission in Part; 2019,* 86 FR 60797 (November 4, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Countervailing Duty Administrative Review of Certain Hot-Rolled Steel Flat Products from the Republic of Korea; 2019: Post-Preliminary Analysis Memorandum,'' dated December 21, 2021 (Post-Preliminary Analysis).

[3] *See* Memorandum, ''Certain Hot-Rolled Steel Flat Products from the Republic of Korea: Extension of Deadline for Final Results of Countervailing Duty Administrative Review,'' dated February 25, 2022.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019 Administrative Review of the Countervailing Duty Order on Certain Hot-Rolled Steel Flat Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] This company was also referenced as ''Hyundai Steel Co., Ltd.'' in the initiation notice. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 78990 (December 8, 2020).

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notice to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: May 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

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

[FR Doc. 2022–09913 Filed 5–6–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC017]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Halibut and Sablefish Individual Fishing Quota Committee (IFQ Committee) will meet May 26, 2022.

DATES: The meeting will be held on Thursday, May 26, 2022, from 8 a.m. to 2 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2933*.

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Sam Cunningham, Council staff; phone: (907) 271–2809; email: *sam.cunningham@noaa.gov*. For technical support, please contact our admin Council staff, email: *npfmc.admin@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, May 26, 2022

The IFQ Committee agenda will include: (a) Update on Emergency Rule requests; (b) update on IFQ Omnibus amendment packages; (c) update on Recreational Quota Entity (RQE) and Catch Sharing Plan (CSP); (d) medical quota transfers; (e) area 4 vessel cap proposal; (f) review IFQ task list; (g) prioritization polling for members and poll results; and (h) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2933* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2933*.

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2933*.

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

Dated: May 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–09880 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB983]

Taking of Marine Mammals Incidental to Specific Activities

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

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the City of Hoonah (City) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates. The initial IHA authorized take of nine species of marine mammals, by Level A and Level B harassment, incidental to pile driving activities associated with construction upgrades of a cargo dock at the city-owned Hoonah Marine Industrial Center (HMIC) in Port Frederick Inlet on Chichagof Island in Hoonah, Alaska. The project has been delayed and none of the work covered in the initial IHA has been conducted. The initial IHA was effective from May 7, 2021, through May 6, 2022. The City has requested re-issuance with new effective dates of October 1, 2022 through September 30, 2023. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a second identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from October 1, 2022 through September 30, 2023.

ADDRESSES: An electronic copy of the final 2021 IHA previously issued to the City, the City's application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting *https://www.fisheries.noaa.gov/action/incidental-take-authorization-hoonah-marine-industrial-center-cargo-dock-project-hoonah.* In case of problems accessing these documents, please call the contact

listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Stephanie Egger, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On May 20, 2021, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the City of Hoonah for the Hoonah Marine Industrial Center Cargo Dock Project, Hoonah, Alaska (86 FR 27410). The effective dates of that IHA were May 7, 2021, through May 6, 2022. On February 27, 2022, the City informed NMFS that the project was delayed. None of the work identified in the initial IHA (*e.g.,* pile driving activities) has occurred. The City submitted a request on April 6, 2022 that we reissue an identical IHA that would be effective from October 1, 2022 through September 30, 2023, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, re-issuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The purpose of this project is to make upgrades to the HMIC. Upgrades to the site include the installation of three breasting dolphins, a sheet pile bulk cargo dock, fender piles, and a catwalk. The planned upgrades are needed to continue safely accommodating barges and other vessels delivering essential goods to the City. The planned project at the HMIC is located in Port Frederick Inlet, approximately 0.8 kilometers (km) (0.5 miles) northwest of downtown Hoonah 0.24 km (0.15 miles) east of the State of Alaska Ferry Terminal in Southeast Alaska. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the initial IHA. The mitigation and monitoring are also as prescribed in the initial IHA.

Species that are expected to be taken by the planned activity include: Gray whale (*Eschrichtius robustus*), Minke whale (*Balaenoptera acutorostrata*), Humpback whale (*Megaptera novaeangliae*), Killer whale (*Orcinus orca*), Pacific White-Sided Dolphin (*Lagenorhynchus obliquidens*), Dall's porpoise (*Phocoenoides dalli*), Harbor porpoise (*Phocoena phocoena*), Steller Sea Lion (*Eumetopias jubatus*), and Harbor seal (*Phoca vitulina*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the initial 2021 IHA for the City's construction work (86 FR 27410), the City's application, the **Federal Register** notice of the proposed IHA (86 FR 12630), and all associated references and documents.

Determinations

The City will conduct activities as analyzed in the initial 2021 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued 2022 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will affect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) the City's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we

have not identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the Alaska Regional Office (AKRO).

NMFS is authorizing take of Mexico DPS humpback whales, and Western DPS Steller sea lions, which are listed under the ESA. The Permit and Conservation Division completed a Section 7 consultation with the AKRO for the issuance of this IHA and a biological opinion was issued on May 4, 2021. The AKRO's biological opinion states that the action is not likely to jeopardize the continued existence of Western DPS Steller sea lions or Mexico DPS humpback whales. The May 4, 2021 biological opinion is still in effect.

Authorization

NMFS has issued an IHA to the City for in-water construction activities associated with the specified activity from October 1, 2022 through September 30, 2023. All previously described mitigation, monitoring, and reporting requirements from the initial 2021 IHA are incorporated.

Dated: May 4, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–09924 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC012]

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 Summer Flounder, Scup, and Black Sea Bass Advisory Panel and Bluefish Advisory Panel will hold a public webinar meeting, jointly with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisory Panel and Bluefish Advisory Panel.

DATES: The meeting will be held on Wednesday May 25, 2022, from 9 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 website 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 objectives of this meeting are for the Advisory Panels to: (1) Review the alternatives under consideration in the Recreational Harvest Control Rule Framework/Addenda, (2) review comments received through the addenda public comment period, (3) receive a progress update on the Scientific and Statistical Committee's review of this action, and (4) provide recommendations to the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission regarding preferred alternatives.

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: May 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–09877 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC016]

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 Ecosystem-Based Fishery Management Committee 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, May 31, 2022, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/6461673028973745678*.

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 EBFM Committee will meet to receive an update and discuss the following issues: Initial outreach and preparation for public information workshops on Ecosystem-Based Fishery Management for Georges Bank; and planning to conduct a Prototype Management Strategy Evaluation of Georges Bank Ecosystem-Based Fishery Management strategies and progress toward hiring of a contractor to conduct it. Other business will be discussed as 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: May 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–09879 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC015]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public joint meeting of its Habitat 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 meeting will be held on Tuesday, May 24, 2022, at 1 p.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/6837593855468696331*.

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 Essential Fish Habitat Consultation process, including the Council's role and recent projects. They will also discuss Council action considering designation of a Habitat Area of Particular Concern in Southern New England, including objectives, range of alternatives, and supporting information and potentially recommend preferred alternatives to the Habitat Committee. Other business may be discussed as necessary.

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 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.

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 date. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: May 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–09878 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC013]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Pacific Northwest Crab Industry Advisory Committee (PNCIAC) will meet May 25, 2022.

DATES: The meeting will be held on Wednesday, May 25, 2022, from 9 a.m. to 11 a.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2938.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Sarah Marrinan, Council staff; phone: (907) 271–2809; email: *sarah.marrinan@noaa.gov.* For technical support please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Wednesday, May 25, 2022

The Committee will discuss: (a) Red king crab including voluntary measures; (b) opilio snow crab rebuilding; (c) Council process changes; and (d) other business. The agenda is subject to change, and the latest version will be posted *https://meetings.npfmc.org/Meeting/Details/2938* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2938.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2938.*

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

Dated: May 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–09908 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC008]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice, Permit Renewal of an Endangered Species Act (ESA) Section

10(a)1(A) scientific enhancement permit.

SUMMARY: Notice is hereby given that NMFS renewed Section 10(a)1(A) scientific enhancement Permit 20085–2R to Stillwater Sciences Inc. (Stillwater). Authorized activities within the permit are expected to affect and enhance the threatened South Central California Coast (SCCC) Distinct Population Segment (DPS) of steelhead (*Oncorhynchus mykiss*) through invasive species removal from a southern California watershed (Chorro Creek) in San Luis Obispo County, California.

ADDRESSES: The permit application, the permit, and other related documents are available for review by contacting the California Coastal Office, Section 10(a)1(A) permit coordinator for southern California (Matt McGoogan: phone: 562–980–4026 or email at: *Matthew.McGoogan@noaa.gov*). The application for Permit 20085–2R is also available for review at the Authorizations and Permits for Protected Species website: *https://apps.nmfs.noaa.gov/search/search.cfm.*

FOR FURTHER INFORMATION CONTACT: Matt McGoogan at 562–980–4026, or email: *Matthew.McGoogan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notification

Threatened SCCC steelhead.

Authority

Scientific research and enhancement 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 222–227). NMFS issues a Section 10(a)1(A) permit based on findings that the permit is (1) applied for in good faith, (2) would not operate to the disadvantage of the listed species which is the subject of the permit, and (3) consistent with the purposes and policies set forth in Section 2 of the ESA. Authority for take exemption of listed species is subject to conditions set forth in the permit.

Permit 20085–2R

A receipt of application notice for Permit 20085–2R was published in the **Federal Register** on August 20, 2021 (86 FR 46832), providing 30 days for public comment prior to permit processing. No comments were received. Permit 20085–2R was issued to Stillwater on October 20, 2021.

Permit 20085–2R authorizes take exemption of threatened SCCC steelhead in association with enhancement activities involving the removal of Sacramento pikeminnow (*Ptychocheilus grandis*) from the Chorro Creek watershed in San Luis Obispo County, California. The primary objectives of this enhancement effort involve: (1) Determining the distribution, abundance, size, and age structures of both pikeminnow and steelhead in the watershed; (2) eliminating pikeminnow from the watershed; (3) developing a plan for long-term pikeminnow management in the watershed; and (4) documenting changes in steelhead abundance and distribution in response to pikeminnow removal. Proposed enhancement activities include: (1) Conducting snorkel surveys to assess abundance and distribution of pikeminnow and steelhead; (2) using backpack electrofishing equipment, seines, hook-and-line sampling, and spearfishing to capture pikeminnow; (3) measuring the weight and length of juvenile steelhead collected during sampling activities; (4) returning the collected steelhead alive and unharmed to Chorro Creek; and (5) humanely euthanizing and disposing pikeminnow.

Permit 20085–2R authorized field activities associated with the enhancement effort to begin on October 20, 2021 (the date the permit was issued), and ceases authorization of the subject activities when the permit expires on December 31, 2031. The annual take exemption of threatened SCCC steelhead that permit 20085–2R authorizes for the subject enhancement effort is as follows: (1) Non-lethal capture and release of up to 1,500 juvenile steelhead while electrofishing, (2) non-lethal capture and release of up to 150 juvenile steelhead while seining, (3) non-lethal capture and release up to 10 juvenile steelhead while hook-and-line fishing, and (4) non-lethal observation of up to 2,000 juvenile and 10 adult steelhead during instream snorkel surveys. The potential annual unintentional lethal take permit 20085–2R authorizes is up to 33 juvenile steelhead. No intentional lethal take of steelhead is authorized or expected as a result of these enhancement activities.

The subject scientific enhancement activities that Permit 20085–2R authorizes are expected to support steelhead recovery in the Chorro Creek watershed and are consistent with recommendations and objectives outlined in NMFS' South Central California Coast Steelhead Recovery Plan. See the application for Permit 20085–2R and issued Permit 20085–2R for greater details on the associated scientific enhancement activities and related methodology authorized with this permit.

Dated: May 3, 2022.

Angela Somma,

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

[FR Doc. 2022–09838 Filed 5–6–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB832]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Off New Jersey by NextEra Energy Transmission MidAtlantic Holdings, LLC

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from NextEra Energy Transmission MidAtlantic Holdings, LLC (NEETMA) for authorization to take marine mammals incidental to high-resolution geophysical (HRG) site characterization surveys off the coast of New Jersey. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year Renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than June 8, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Written comments should be submitted via email to *ITP.Potlock@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On February 4, 2022, NMFS received a request from NextEra Energy Transmission MidAtlantic Holdings, LLC (NEETMA) for an IHA to take marine mammals incidental to marine site characterization surveys occurring in two locations (Northern and Southern survey areas) off the coast of New Jersey in the New Jersey Offshore Transmission Facilities Project (NJOTF or Project). The application was deemed adequate and complete on April 1, 2022. NEETMA's request is for take of a small number of 15 marine mammal species (consisting of 16 stocks) by Level B harassment only. Neither NEETMA nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

NEETMA proposes to conduct HRG and geotechnical surveys as part of the New Jersey Offshore Transmission Facilities Project NJOTF off the coast of New Jersey. The surveys will take place along proposed submarine export cable routes and at locations for potential offshore platforms. Geotechnical survey activities would include the use of vibracores and/or cone penetration tests (CPTs), to identify and characterize the seabed conditions vertically for project planning and design, and to collect data to identify paleolandscapes.

The purpose of the proposed surveys are to support the siting and design of offshore facilities, including offshore platforms for converter stations and offshore submarine transmission cables. As many as three survey vessels may operate concurrently as part of the proposed surveys. Underwater sound resulting from NEETMA's proposed site characterization survey activities, specifically HRG surveys, has the potential to result in incidental take of marine mammals in the form of behavioral harassment.

Dates and Duration

The estimated duration of the activity is expected to consist of up to 320 total survey days over the course of a single year within the two survey areas (Table 1). As multiple vessels (*i.e.,* three survey vessels) may be operating concurrently across both survey areas, each day that a single survey vessel is operating constitutes a single survey day. Therefore, it is expected that the anticipated 320 survey days would occur over a shorter aggregate duration. This schedule is based on 24-hour operations that may be conducted at any time throughout the year. The schedule presented here for this proposed project has accounted for potential down time due to inclement weather or other project-related delays. The IHA would be effective for a period of one year.

TABLE 1—NUMBER OF SURVEY DAYS THAT NEETMA PLANS TO PERFORM THE DESCRIBED HRG SURVEY ACTIVITIES

Survey area	Number of active survey days expected [1]
Northern	248
Southern	72
Total	320

[1] Up to three total survey vessels may be operating within both of the survey areas concurrently.

Specific Geographic Region

NEETMA's proposed activities would occur in the Northwest Atlantic Ocean within Federal and state waters (Figure 1). Surveys would occur in both the Northern and Southern survey areas along potential areas for future offshore

platforms used for converter stations and potential offshore submarine transmission cable routes. NEETMA's proposed activities would occur within the NJOTF. The total site area is approximately 1,861,198 acres (2,908.121 square miles (mi^2); 7,532 square kilometers (km^2)) and extends approximately 51 nautical miles (nm; 59.03 miles (mi); 95 kilometers (km)) offshore at its furthest point with some coastal surveys planned. However, the expected area to be surveyed is much smaller than the total site area, consisting of 6,254 km^2 in the Northern survey area and 1,278 km^2 in the Southern. This equates to approximately 5,183.97 km^2 of ensonified area over the duration of the activities.

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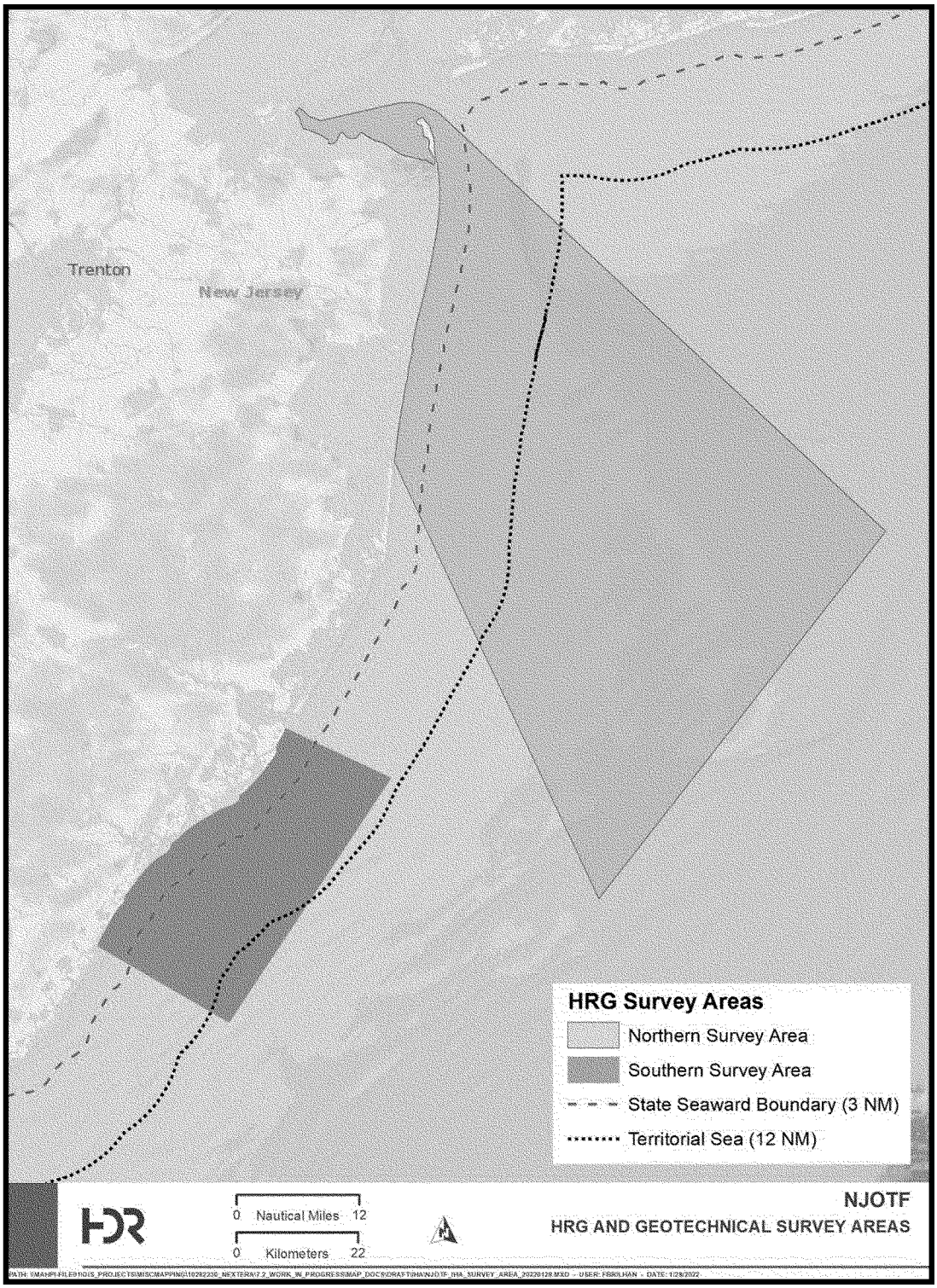

Figure 1– Proposed survey areas for the New Jersey Offshore Transmission Facilities Project (NJOTF Project) HRG&G Surveys.

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Detailed Description of Specific Activity

NEETMA's proposed marine site characterization surveys include HRG and geotechnical survey activities. These surveys would occur within both the Northern and Southern areas off New Jersey, as specified in Figure 1. The Northern and Southern Project areas are

approximately 7,532 km² (1,861,197.73 acres) and are located approximately 95 kilometers offshore of New Jersey at the furthest point. For the purposes of this proposed IHA, both the Northern and Southern areas are collectively referred to as the survey sites. NEETMA's survey activities are anticipated to be supported by vessels, which will maintain a speed of approximately to 4 knots (kn; 7.4 kilometer per hour (km/h)) while transiting survey lines. The proposed HRG and geotechnical survey activities are described below.

Proposed Geotechnical Survey Activities

NEETMA's proposed geotechnical activities would include the drilling of vibracores and/or CPTs. Similar proposed activities have been previously analyzed, *e.g.,* see the proposed 2020 **Federal Register** notice (85 FR 7926; February 12, 2020) and the proposed 2022 **Federal Register** notice (87 FR 4200; January 27, 2022) for Atlantic Shores' site characterization surveys. The same discussion by NMFS to not analyze the geotechnical activities further that was included in that notice (*i.e.,* as they do not constitute take of marine mammals) was determined to apply to this proposed project. In these notifications, NMFS determined that the likelihood of the proposed geotechnical surveys resulting in harassment of marine mammals was to be so low as to be discountable. As this information remains applicable and NMFS' determination has not changed, these activities will not be discussed further in this proposed notification.

Proposed Geophysical Survey Activities

NEETMA has proposed that HRG survey operations would be conducted continuously 24 hours a day. Based on 24-hour operations, the estimated total duration of the proposed activities would be approximately 320 survey days. This includes 248 days of survey activities in the Northern area and 72 days in the Southern area (refer back to Table 1). As previously discussed above, this schedule does include potential down time due to inclement weather or other project-related delays. The HRG survey activities will be supported by vessels of sufficient size to accomplish the survey goals in each of the specified survey areas. It is assumed surveys in both of the identified survey areas will be executed by a total of three vessels during any given campaign (*i.e.,* up to three vessels operating collectively across the 320 days of the proposed project but each vessel may operate concurrently in either the Northern or Southern survey areas). HRG survey equipment will either be mounted to or towed behind the survey at a typical survey speed of approximately 4 knot (7.4 km per hour).

The geophysical survey activities proposed by NEETMA may include the use of the following equipment:

- Shallow Penetration Sub-bottom Profilers (SBPs; Compressed High-Intensity Radiated Pulses [CHIRPs]);
- Medium penetration SBPs (Boomers);
- Medium penetration SBPs (Sparkers);
- Parametric SBPs, also called sediment echosounders;
- Ultra-short Baseline (USBL) Positioning and Global Acoustic Positioning System (GAPS);
- Multibeam echosounder (MBES); and
- Seafloor imaging (sidescan sonar).

However, not all of the equipment described above has the potential to harass marine mammals. The MBES and sidescan sonar are known to produce sounds outside the hearing range of marine mammals (≤180 kHz); therefore these are not discussed further in this notice as they are not expected to cause harassment. Specifically due to its functionality and source characteristics as USBLs are primarily used to locate the position(s) of other HRG equipment, USBLs are not expected to have the reasonable potential to cause harassment of marine mammals. Lastly, parametric SBPs tend to operate at high frequencies with very narrow beamwidth, which results in small harassment zones (<4 m). Further, due to the size of the Level B harassment zones produced by these acoustic sources, both NMFS and NEETMA do not expect harassment to occur. Therefore, and as noted in the IHA application, NMFS concurs that the shallow and medium SBPs (Sparkers, Boomers, and CHIRPs) have the potential to cause harassment to marine mammals.

Table 2 identifies the representative survey equipment that may be used in support of planned geophysical survey activities that may also cause the take of marine mammals. The make and model of the listed equipment may vary depending on availability and the final equipment choices will vary depending upon the final survey design, vessel availability, and survey contractor selection. Geophysical surveys are expected to use several equipment types concurrently in order to collect multiple aspects of geophysical data along one transect. Selection of equipment combinations is based on specific survey objectives. All categories of representative HRG survey equipment shown in Table 2 work with operating frequencies <180 kHz.

TABLE 2—SUMMARY OF REPRESENTATIVE EQUIPMENT SPECIFICATIONS WITH OPERATING FREQUENCIES BELOW 180 KHZ

Equipment category	HRG survey equipment type	Operating frequency ranges (kHZ)	Operational source level ranges (dB re 1 μPa m)	Source $level_{0\text{-}peak}$ (dB re 1 μPa m)	Beamwidth ranges (degrees)	Typical pulse durations (millisecond)	Pulse repetition rate (Hz)
Non-Parametric Shallow Penetration SBPS (Non-Impulsive)							
CHIRPs	ET 216 (2000DS or 3200 top unit)	2–16 2–8	195		24	20	6
	ET 424	4–24	176		71	3.4	2
	ET 512	0.7–12	179		80	9	8
	GeoPulse 5430A	2–17	196		55	50	10
	Teledyne Benthose Chirp III—TTV 170	2–7	197		100	60	15
Medium Penetration SBPs (Impulsive)							
Sparker	AA, Dura-spark UHD (400 tips, 500 J) [1]	0.3–1.2	203	211	Omnidirectional	1.1	4
	GeoMarine Geo Spark 2000 (400 tip) [1]	0.05–3	203	213	Omnidirectional	3.4	1
Boomer	AA, triple plate S-Boom (700–1,000 J) [2]	0.1–5	205	211	80	0.6	4

Note: —= not applicable; μPa = micropascal; AA = Applied Acoustics; dB = decibel; ET = EdgeTech; J = joule; Omni = omnidirectional source; re = referenced to; SL = source level; 0–PK = zero-to-peak; RMS = root mean squared; UHD = ultra-high definition.

[1] The Dura-spark measurements and specifications provided in Crocker and Fratantonio (2016) were used for all sparker systems proposed for the survey. These include variants of the Dura-spark sparker system and various configurations of the GeoMarine Geo-Source sparker system. The data provided in Crocker and Fratantonio (2016) represent the most applicable data for similar sparker systems with comparable operating methods and settings when manufacturer or other reliable measurements are not available.

[2] Crocker and Fratantonio (2016) provide S-Boom measurements using two different power sources (CSP–D700 and CSP–N). The CSP–D700 power source was used in the 700 J measurements but not in the 1,000 J measurements. The CSP–N source was measured for both 700 J and 1,000 J operations but resulted in a lower SL; therefore, the single maximum SL value was used for both operational levels of the S-Boom.

The deployment of HRG survey equipment, including the equipment planned for use during NEETMA's proposed activities, produces sound in the marine environment that has the potential to result in harassment of marine mammals. Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of NEETMA's application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species).*

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2021). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' draft 2021 SARs. All values presented in Table 3 are the most recent available at the time of publication and are available in the draft 2021 SARs available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 3—MARINE MAMMAL SPECIES LIKELY TO OCCUR NEAR THE PROJECT AREA THAT MAY BE AFFECTED BY NEETMA'S ACTIVITY

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
North Atlantic right whale ..	*Eubalaena glacialis*	Western North Atlantic	E/D, Y	368 (0; 356; 2020) [5 6]	0.8	18.6
Fin whale	*Balaenoptera physalus*	Western North Atlantic	E/D, Y	6,802 (0.24; 5,573; 2016)	11	2.35
Humpback whale	*Megaptera novaengliae*	Gulf of Maine	-/-, Y	1,396 (0; 1,380; 2016)	22	12.15
Minke whale	*Balaenoptera acutorostrata*	Canadian East Coastal	-/-, N	21,968 (0.31; 17,002; 2016)	170	10.6
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Sperm whale	*Physeter macrocephalus*	North Atlantic	E/D, Y	4,349 (0.28; 3,451; 2016)	3.9	0
Risso's dolphin	*Grampus griseus*	Western North Atlantic	-/-, N	35,493 (0.19; 30,289; 2016)	303	54.3
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic	-/-, N	39,215 (0.3; 30,627; 2016)	306	21
Short-finned pilot whale	*Globicephala macrorhynchus*	Western North Atlantic	-/-, Y	28,924 (0.24; 23,637, 2016)	236	136
Atlantic white-sided dolphin.	*Lagenorhynchus acutus*	Western North Atlantic	-/-, N	93,233 (0.71; 54,443; 2016)	544	26
Common dolphin	*Delphinus delphis*	Western North Atlantic	-/-, Y	172,897 (0.21, 145,216, 2016) ...	526	399
Common bottlenose dolphin.	*Tursiops truncatus*	Western North Atlantic—Offshore.	-/-, N	62,851 (0.23; 51,914; 2016)	519	28
		Western North Atlantic—Coastal Migratory.	-/D, Y	6,639 (0.41; 4,759; 2016)	48	12.2–21.5
Atlantic spotted dolphin	*Stenella frontalis*	Western North Atlantic	-/-, N	39,921 (0.27; 32,032; 2016)	320	0
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy.	-/-, N	95,543 (0.31; 74,034; 2016)	851	217
Order Carnivora—Superfamily Pinnipedia						
Harbor seal	*Phoca vitulina*	Western North Atlantic	-/-, N	75,834 (0.15; 66,884; 2012)	2006	350
Gray seal	*Halichoerus grypus*	Western North Atlantic	-/-, N	27,131 (0.19; 23,158; 2016)	1389	4,729

[1] ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is the coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike).

[4] NMFS' stock abundance estimate (and associated PBR value) applies to U.S. population only. Total stock abundance (including animals in Canada) is approximately 451,431. The annual M/SI value given is for the total stock.

[5] Abundance source is Pace *et al.* (2021). PBR and annual M/SI source is final 2020 SAR (Hayes *et al.* 2020). Because PBR is based on the minimum population estimate, we anticipate it will be slightly lower than what is presented here given the Pace *et al.* (2021) abundance. Regardless of final numbers, NMFS recognizes the NARW stock is critically endangered with a low PRB and high annual M/SI rate due primarily to ship strikes and entanglement

[6] The draft 2022 SARs have yet to be released; however, NMFS has updated its species web page to recognize the population estimate for NARWs is now below 350 animals (*https://www.fisheries.noaa.gov/species/north-atlantic-right-whale*).

As indicated above, all 15 species (with 16 managed stocks) in Table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing.

The temporal and/or spatial occurrence of several cetacean and pinniped species is such that take of these species is not expected to occur either because they have very low densities in the survey area or are known to occur further offshore than the survey area. These include: Cuvier's beaked whale (*Ziphius cavirostris*), four species of Mesoplodont beaked whale (*Mesoplodon spp.*), dwarf and pygmy sperm whale (*Kogia sima and Kogia breviceps*), northern bottlenose whale (*Hyperoodon ampullatus*), killer whale (*Orcinus orca*), pygmy killer whale (*Feresa attenuata*), false killer whale (*Pseudorca crassidens*), melon-headed whale (*Peponocephala electra*), striped dolphin (*Stenella coeruleoalba*), white-beaked dolphin (*Lagenorhynchus albirostris*), pantropical spotted dolphin (*Stenella attenuata*), Fraser's dolphin (*Lagenodelphis hosei*), rough-toothed dolphin (*Steno bredanensis*), Clymene dolphin (*Stenella clymene*), spinner dolphin (*Stenella longirostris*), hooded seal (*Cystophora cristata*), and harp seal (*Pagophilus groenlandicus*). Furthermore, based on the density data presented in NEETMA's application, NMFS considers it unlikely for sei whales (*Balaenoptera borealis*) and blue whales (*Balaenoptera musculus*) to occur in the project area due to the near-zero density estimates for both cetacean species. As harassment and subsequent take of these species is not anticipated as a result of the proposed activities, these species are not analyzed or discussed further.

In addition, the Florida manatee (*Trichechus manatus;* a sub-species of the West Indian manatee) has been previously documented as an occasional visitor the Northeast region during summer months (U.S. Fish and Wildlife Service (USFWS) 2019). However, manatees are managed by the USFWS and are not considered further in this document.

Recently, NMFS has updated its species web page to recognize the population estimate for NARWs is now below 350 animals (*https://www.fisheries.noaa.gov/species/north-atlantic-right-whale*). We anticipate this to be more formalized in the draft 2022 SAR.

For the majority of species potentially present in the specific geographic region, NMFS has designated only a single generic stock (*e.g.,* ''western North Atlantic'') for management purposes. This includes the ''Canadian east coast'' stock of minke whales, which includes all minke whales found in U.S. waters and is also a generic stock for management purposes. For humpback whales, NMFS defines stocks on the basis of feeding locations, *i.e.,* Gulf of Maine. However, references to humpback whales in this document refer to any individuals of the species that are found in the specific geographic region. Additional information on these species can be found in Sections 3 and 4 of NEETMA's IHA application, the draft 2021 SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*), and NMFS' website (*https://www.fisheries.noaa.gov/find-species).*

Below is a description of the species that have the highest likelihood of occurring in the survey area and are thus expected to potentially be taken by the proposed activities as well as further detail informing the baseline for select species (*i.e.,* information regarding current Unusual Mortality Events (UMEs) and important habitat areas).

North Atlantic Right Whale

The North Atlantic right whale ranges from calving grounds in the southeastern United States to feeding grounds in New England waters and into Canadian waters (Hayes *et al.,* 2018). Surveys have demonstrated the existence of seven areas where North Atlantic right whales congregate seasonally, including north and east of the proposed survey area in Georges Bank, off Cape Cod, and in Massachusetts Bay (Hayes *et al.,* 2018). In the late fall months (*e.g.,* October), right whales are generally thought to depart from the feeding grounds in the North Atlantic and move south to their calving grounds off Georgia and Florida. However, recent research indicates our understanding of their movement patterns remains incomplete (Davis *et al.,* 2017). A review of passive acoustic monitoring data from 2004 to 2014 throughout the western North Atlantic demonstrated nearly continuous year-round right whale presence across their entire habitat range (for at least some individuals), including in locations previously thought of as migratory corridors, suggesting that not all of the population undergoes a consistent annual migration (Davis *et al.,* 2017). However, given that NEETMA's surveys would be concentrated offshore New Jersey, any right whales in the vicinity of the survey areas are expected to be transient, most likely migrating through the area.

The western North Atlantic population demonstrated overall growth of 2.8 percent per year between 1990 to 2010, despite a decline in 1993 and no growth between 1997 and 2000 (Pace *et al.,* 2017). However, since 2010 the population has been in decline, with a 99.99 percent probability of a decline of just under 1 percent per year (Pace *et al.,* 2017). Between 1990 and 2015, calving rates varied substantially, with low calving rates coinciding with all three periods of decline or no growth (Pace *et al.,* 2017). On average, North Atlantic right whale calving rates are estimated to be roughly half that of southern right whales (*Eubalaena australis*) (Pace *et al.,* 2017), which are increasing in abundance (NMFS, 2015). In 2018, no new North Atlantic right whale calves were documented in their calving grounds; this represented the first time since annual NOAA aerial surveys began in 1989 that no new right whale calves were observed. Eighteen right whale calves were documented in 2021. As of March 16, 2022 and the writing of this proposed Notice, 15 North Atlantic right whale calves have documented to have been born during this calving season. Presently, the best available population estimate for North Atlantic right whales is 368 per the draft 2021 SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*).

The proposed survey area is part of a migratory corridor Biologically Important Area (BIA) for North Atlantic right whales (effective March–April and November–December) that extends from Massachusetts to Florida (LeBrecque *et al.,* 2015). Off the coast of New Jersey,

the migratory BIA extends from the coast to beyond the shelf break. This important migratory area is approximately 269,488 km² in size (compared with the approximately 5,183.97 km² of total estimated Level B harassment ensonified area associated with the 320 planned survey days) and is comprised of the waters of the continental shelf offshore the East Coast of the United States, extending from Florida through Massachusetts. NMFS' regulations at 50 CFR part 224.105 designated nearshore waters of the Mid-Atlantic Bight as Mid-Atlantic U.S. Seasonal Management Areas (SMA) for right whales in 2008. SMAs were developed to reduce the threat of collisions between ships and right whales around their migratory route and calving grounds. A portion of one SMA, which occurs off the mouth of Delaware Bay, overlaps spatially with a section of the proposed survey area. The SMA, which occurs off the mouth of Delaware Bay, is active from November 1 through April 30 of each year. Within SMAs, the regulations require a mandatory vessel speed (less than 10 kn) for all vessels greater than 65 ft. A portion of one SMA overlaps spatially with the northern section of the proposed survey area.

Elevated North Atlantic right whale mortalities have occurred since June 7, 2017, along the U.S. and Canadian coast. This event has been declared an Unusual Mortality Event (UME), with human interactions, including entanglement in fixed fishing gear and vessel strikes, implicated in at least 15 of the mortalities thus far. As of April 14, 2022, a total of 34 confirmed dead stranded whales (21 in Canada; 13 in the United States) have been documented. The cumulative total number of animals in the North Atlantic right whale UME has been updated to 49 individuals to include both the confirmed mortalities (dead stranded or floaters) (n=34) and seriously injured free-swimming whales (n=15) to better reflect the confirmed number of whales likely removed from the population during the UME and more accurately reflect the population impacts. More information is available online at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2021-north-atlantic-right-whale-unusual-mortality-event.*

Right Whale Slow Zones are areas where mariners are encouraged to avoid areas and/or reduce speeds to 10 kn to avoid vessel collisions with North Atlantic right whales. Slow Zones typically persist for 15 days. More information on these right whale Slow Zones can be found on NMFS' website (*https://www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-vessel-strikes-north-atlantic-right-whales*).

Humpback Whale

Humpback whales are found worldwide in all oceans. Humpback whales were listed as endangered under the Endangered Species Conservation Act (ESCA) in June 1970. In 1973, the ESA replaced the ESCA, and humpbacks continued to be listed as endangered. On September 8, 2016, NMFS divided the species into 14 distinct population segments (DPS), removed the current species-level listing, and in its place listed four DPSs as endangered and one DPS as threatened (81 FR 62259; September 8, 2016). The remaining nine DPSs were not listed. The West Indies DPS, which is not listed under the ESA, is the only DPS of humpback whale that is expected to occur in the survey area. Whales occurring in the survey area are not necessarily from the Gulf of Maine feeding population managed as a stock by NMFS. Barco *et al.* (2002) estimated that, based on photo-identification, only 39 percent of individual humpback whales observed along the mid- and south Atlantic U.S. coast are from the Gulf of Maine stock. Bettridge *et al.* (2015) estimated the size of the West Indies DPS population at 12,312 (95 percent CI 8,688–15,954) whales in 2004–05, which is consistent with previous population estimates of approximately 10,000–11,000 whales (Stevick *et al.,* 2003; Smith *et al.,* 1999) and the increasing trend for the West Indies DPS (Bettridge *et al.,* 2015).

Humpback whales utilize the mid-Atlantic as a migration pathway between calving/mating grounds to the south and feeding grounds in the north (Waring *et al.,* 2007a; Waring *et al.,* 2007b). Barco *et al.* (2002) suggested that the mid-Atlantic region primarily represents a supplemental winter-feeding ground used by humpbacks. Recent research by King *et al.* (2021) has demonstrated a higher occurrence and use (foraging) of the New York Bight area by humpback whales than previously known.

Three previous UMEs involving humpback whales have occurred since 2000, in 2003, 2005, and 2006. Since January 2016, elevated humpback whale mortalities have occurred along the Atlantic coast from Maine to Florida. Partial or full necropsy examinations have been conducted on approximately half of the 158 known cases (as of April 14, 2022). Of the whales examined, about 50 percent had evidence of human interaction, either ship strike or entanglement. While a portion of the whales have shown evidence of pre-mortem vessel strike, this finding is not consistent across all whales examined and more research is needed. NOAA is consulting with researchers that are conducting studies on the humpback whale populations, and these efforts may provide information on changes in whale distribution and habitat use that could provide additional insight into how these vessel interactions occurred. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2016-2021-humpback-whale-unusual-mortality-event-along-atlantic-coast.*

Fin Whale

Fin whales are common in waters of the U. S. Atlantic Exclusive Economic Zone (EEZ), principally from Cape Hatteras northward (Waring *et al.,* 2016). Fin whales are present north of 35-degree latitude in every season and are broadly distributed throughout the western North Atlantic for most of the year (Waring *et al.,* 2016). They are typically found in small groups of up to five individuals (Brueggeman *et al.,* 1987). The main threats to fin whales are fishery interactions and vessel collisions (Waring *et al.,* 2016).

Minke Whale

Minke whales can be found in temperate, tropical, and high-latitude waters. The Canadian East Coast stock can be found in the area from the western half of the Davis Strait (45° W) to the Gulf of Mexico (Waring *et al.,* 2016). This species generally occupies waters less than 100-m deep on the continental shelf. There appears to be a strong seasonal component to minke whale distribution in the survey areas, in which spring to fall are times of relatively widespread and common occurrence while during winter the species appears to be largely absent (Waring *et al.,* 2016).

Since January 2017, elevated minke whale mortalities have occurred along the Atlantic coast from Maine through South Carolina, with a total of 122 strandings (as of April 14, 2022). This event has been declared a UME. Full or partial necropsy examinations were conducted on more than 60 percent of the whales. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease, but these findings are not consistent across all of the whales examined, so more research is needed. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2021-minke-whale-unusual-mortality-event-along-atlantic-coast.*

Sperm Whale

The distribution of the sperm whale in the U.S. EEZ occurs on the continental shelf edge, over the continental slope, and into mid-ocean regions (Waring *et al.,* 2014). The basic social unit of the sperm whale appears to be the mixed school of adult females plus their calves and some juveniles of both sexes, normally numbering 20–40 animals in all. There is evidence that some social bonds persist for many years (Christal *et al.,* 1998). This species forms stable social groups, site fidelity, and latitudinal range limitations in groups of females and juveniles (Whitehead, 2002). In summer, the distribution of sperm whales includes the area east and north of Georges Bank and into the Northeast Channel region, as well as the continental shelf (inshore of the 100-m isobath) south of New England. In the fall, sperm whale occurrence south of New England on the continental shelf is at its highest level, and there remains a continental shelf edge occurrence in the mid-Atlantic bight. In winter, sperm whales are concentrated east and northeast of Cape Hatteras.

Long-Finned Pilot Whale

Long-finned pilot whales are found from North Carolina to Iceland, Greenland and the Barents Sea (Hayes *et al.,* 2021). In the U.S. Atlantic waters the species is distributed principally along the continental shelf edge off the northeastern U.S. coast in winter and early spring and in late spring, pilot whales move onto Georges Bank and into the Gulf of Maine northward, and remain in these areas through late fall (Hayes *et al.,* 2021). Long-finned and short-finned pilot whales overlap spatially along the mid-Atlantic shelf break between Delaware and the southern flank of Georges Bank. Long-finned pilot whales have occasionally been observed stranded as far south as South Carolina, but sightings of long-finned pilot whales south of Cape Hatteras would be considered unusual (Hayes *et al.,* 2021). The main threats to this species include interactions with fisheries and habitat issues including exposure to high levels of polychlorinated biphenyls and chlorinated pesticides, and toxic metals including mercury, lead, and cadmium, and selenium (Hayes *et al.,* 2021).

Short-Finned Pilot Whale

As described above, long-finned and short-finned pilot whales overlap spatially with the survey area and along the mid-Atlantic shelf. There is limited information on the distribution of short-finned pilot whales. They prefer warmer tropical waters and deeper waters offshore, and in the northeastern United States they are often sighted near the Gulf Stream (Hayes *et al.,* 2021). Short-finned pilot whales have occasionally been observed stranded as far north as Massachusetts but north of ~42° N short-finned pilot whale sightings would be considered unusual while south of Cape Hatteras most pilot whales would expected to be short-finned pilot whales (Hayes *et al.,* 2021). As with long-finned pilot whales, the main threats to this species include interactions with fisheries and habitat issues including exposure to high levels of polychlorinated biphenyls and chlorinated pesticides, and toxic metals including mercury, lead, cadmium, and selenium (Hayes *et al.,* 2021).

Atlantic White-Sided Dolphin

White-sided dolphins are found in temperate and sub-polar waters of the North Atlantic, primarily in continental shelf waters to the 100m depth contour from central West Greenland to North Carolina (Waring *et al.,* 2016). The Gulf of Maine stock is most common in continental shelf waters from Hudson Canyon to Georges Bank, and in the Gulf of Maine and lower Bay of Fundy. Sighting data indicate seasonal shifts in distribution (Northridge *et al.,* 1997). During January to May, low numbers of white-sided dolphins are found from Georges Bank to Jeffreys Ledge (off New Hampshire), with even lower numbers south of Georges Bank, as documented by a few strandings collected on beaches of Virginia to South Carolina. From June through September, large numbers of white-sided dolphins are found from Georges Bank to the lower Bay of Fundy. From October to December, white-sided dolphins occur at intermediate densities from southern Georges Bank to southern Gulf of Maine (Payne and Heinemann, 1990). Sightings south of Georges Bank, particularly around Hudson Canyon, occur year round but at low densities.

Atlantic Spotted Dolphin

Atlantic spotted dolphins are found in tropical and warm temperate waters ranging from southern New England, south to Gulf of Mexico and the Caribbean to Venezuela (Waring *et al.,* 2014). This stock regularly occurs in continental shelf waters south of Cape Hatteras and in continental shelf edge and continental slope waters north of this region (Waring *et al.,* 2014). There are two forms of this species, with the larger ecotype inhabiting the continental shelf and is usually found inside or near the 200-m isobaths (Waring *et al.,* 2014).

Common Dolphin

The common dolphin is found worldwide in temperate to subtropical seas. In the North Atlantic, common dolphins are commonly found over the continental shelf between the 100-m and 2,000-m isobaths and over prominent underwater topography and east to the mid-Atlantic Ridge (Waring *et al.,* 2016).

Bottlenose Dolphin

There are two distinct bottlenose dolphin morphotypes in the western North Atlantic: The coastal and offshore forms (Waring *et al.,* 2016). The offshore form is distributed primarily along the outer continental shelf and continental slope in the Northwest Atlantic Ocean from Georges Bank to the Florida Keys. The coastal morphotype is morphologically and genetically distinct from the larger, more robust morphotype that occupies habitats further offshore. Spatial distribution data, tag-telemetry studies, photo-ID studies and genetic studies demonstrate the existence of a distinct Northern Migratory stock of coastal bottlenose dolphins (Waring *et al.,* 2014). During summer months (July–August), this stock occupies coastal waters from the shoreline to approximately the 25-m isobath between the Chesapeake Bay mouth and Long Island, New York; during winter months (January–March), the stock occupies coastal waters from Cape Lookout, North Carolina, to the North Carolina/Virginia border (Waring *et al.,* 2014). The Western North Atlantic northern migratory coastal stock and the Western North Atlantic offshore stock may be encountered by the proposed survey.

Harbor Porpoise

In the Lease Area, only the Gulf of Maine/Bay of Fundy stock may be present. This stock is found in U.S. and Canadian Atlantic waters and is concentrated in the northern Gulf of Maine and southern Bay of Fundy region, generally in waters less than 150-m deep (Waring *et al.,* 2016). They are seen from the coastline to deep waters (>1,800-m; Westgate *et al.,* 1998), although the majority of the population is found over the continental shelf (Waring *et al.,* 2016). The main threat to the species is interactions with fisheries, with documented take in the U.S. northeast sink gillnet, mid-Atlantic gillnet, and northeast bottom trawl fisheries and in the Canadian herring weir fisheries (Waring *et al.,* 2016).

Pinninpeds (Harbor Seal and Gray Seal)

The harbor seal is found in all nearshore waters of the North Atlantic

and North Pacific Oceans and adjoining seas above about 30° N (Burns, 2009). In the western North Atlantic, harbor seals are distributed from the eastern Canadian Arctic and Greenland south to southern New England and New York, and occasionally to the Carolinas (Waring *et al.,* 2016). Haul-out and pupping sites are located off Manomet, MA and the Isles of Shoals, ME, but generally do not occur in areas in southern New England (Waring *et al.,* 2016).

There are three major populations of gray seals found in the world; eastern Canada (western North Atlantic stock), northwestern Europe and the Baltic Sea. Gray seals in the survey area belong to the western North Atlantic stock. The range for this stock is thought to be from New Jersey to Labrador. Current population trends show that gray seal abundance is likely increasing in the U.S. Atlantic EEZ (Waring *et al.,* 2016). Although the rate of increase is unknown, surveys conducted since their arrival in the 1980s indicate a steady increase in abundance in both Maine and Massachusetts (Waring *et al.,* 2016). It is believed that recolonization by Canadian gray seals is the source of the U.S. population (Waring *et al.,* 2016).

Since July 2018, elevated numbers of harbor seal and gray seal mortalities have occurred across Maine, New Hampshire and Massachusetts. This event has been declared a UME. Additionally, stranded seals have shown clinical signs as far south as Virginia, although not in elevated numbers, therefore the UME investigation now encompasses all seal strandings from Maine to Virginia. Ice seals (harp and hooded seals) have also started stranding with clinical signs, again not in elevated numbers, and those two seal species have also been added to the UME investigation. A total of 3,152 reported strandings (of all species) had occurred from July 1, 2018, through March 13, 2020. Full or partial necropsy examinations have been conducted on some of the seals and samples have been collected for testing. Based on tests conducted thus far, the main pathogen found in the seals is phocine distemper virus. NMFS is performing additional testing to identify any other factors that may be involved in this UME. Presently, this UME is non-active and is pending closure by NMFS as of March 2020. Information on this UME is available online at: *www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018-2020-pinniped-unusual-mortality-event-along.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range [1]
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

[1] Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Fifteen marine mammal species (thirteen cetacean and two pinniped (both phocid) species) have the reasonable potential to co-occur with the proposed survey activities. Please refer back to Table 3. Of the cetacean species that may be present, four are classified as low-frequency cetaceans (*i.e.,* all mysticete species), eight are classified as mid-frequency cetaceans (*i.e.,* all delphinid and the sperm whale), and one is classified as a high-frequency cetaceans (*i.e.,* harbor porpoise).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. Detailed descriptions of the potential effects of similar specified activities have been provided in other recent and related **Federal Register** notices, including for survey activities using similar HRG methodologies, over similar amounts of time, and occurring within the Mid-Atlantic region,

including waters off New Jersey (*e.g.,* 82 FR 20563, May 3, 2017; 85 FR 7926, February 12, 2020; 85 FR 37848, June 24, 2020; 86 FR 16327, March 29, 2021; and 87 FR 14823, March 16, 2022). No significant new information is available, and we refer the reader to these documents rather than repeating the details here.

The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the potential effects of the specified activity, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Background on Active Acoustic Sound Sources and Acoustic Terminology

This subsection contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to the summary of the potential effects of the specified activity on marine mammals. For general information on sound and its interaction with the marine environment, please see, *e.g.,* Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983).

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness'' of a sound and is typically described using the relative unit of the decibel. A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)), and is a logarithmic unit that accounts for large variations in amplitude. Therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1-m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 μPa^2-s) represents the total energy in a stated frequency band over a stated time interval or event and considers both intensity and duration of exposure. The per-pulse SEL is calculated over the time window containing the entire pulse (*i.e.,* 100 percent of the acoustic energy). SEL is a cumulative metric; it can be accumulated over a single pulse, or calculated over periods containing multiple pulses. Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source and is represented in the same units as the rms sound pressure.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be directed either in a beam or in beams or may radiate in all directions (omnidirectional sources). The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly.

The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals. Details of source types are described in the following text.

Sounds are often considered to fall into one of two general types: Pulsed and non-pulsed (defined in the following). The distinction between

these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts. The distinction between these two sound types is not always obvious, as certain signals share properties of both pulsed and non-pulsed sounds. A signal near a source could be categorized as a pulse, but due to propagation effects as it moves farther from the source, the signal duration becomes longer (*e.g.,* Greene and Richardson, 1988).

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Sparkers and boomers produce pulsed signals with energy in the frequency ranges specified in Table 2. The amplitude of the acoustic wave emitted from sparker sources is equal in all directions (*i.e.,* omnidirectional), while other sources planned for use during the proposed surveys have some degree of directionality to the beam, as specified in Table 2. Other sources planned for use during the proposed survey activity (*e.g.,* CHIRP SBPs) should be considered non-pulsed, intermittent sources.

Summary on Specific Potential Effects of Acoustic Sound Sources

Underwater sound from active acoustic sources can include one or more of the following: temporary or permanent hearing impairment, behavioral disturbance, masking, stress, and non-auditory physical effects. The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS; permanent threshold shift), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS; temporary threshold shift), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007).

Animals in the vicinity of NEETMA's proposed HRG survey activity are unlikely to incur even TTS due to the characteristics of the sound sources, which include relatively low source levels (176 to 205 dB re 1 µPa m), and generally very short pulses and potential duration of exposure. These characteristics mean that instantaneous exposure is unlikely to cause TTS, as it is unlikely that exposure would occur close enough to the vessel for received levels to exceed peak pressure TTS criteria, and that the cumulative duration of exposure would be insufficient to exceed cumulative sound exposure level (SEL) criteria. Even for high-frequency cetacean species (*e.g.,* harbor porpoises), which have the greatest sensitivity to potential TTS, individuals would have to make a very close approach and also remain very close to vessels operating these sources in order to receive multiple exposures at relatively high levels, as would be necessary to cause TTS. Intermittent exposures—as would occur due to the brief, transient signals produced by these sources—require a higher cumulative SEL to induce TTS than would continuous exposures of the same duration (*i.e.,* intermittent exposure results in lower levels of TTS). Moreover, most marine mammals would more likely avoid a loud sound source rather than swim in such close proximity as to result in TTS. Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when a sub-bottom profiler emits a pulse is small—because if the animal was in the area, it would have to pass the transducer at close range in order to be subjected to sound levels that could cause TTS and would likely exhibit avoidance behavior to the area near the transducer rather than swim through at such a close range. Further, the restricted beam shape of many of HRG survey devices planned for use (Table 2) makes it unlikely that an animal would be exposed more than briefly during the passage of the vessel.

Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal.

In addition, sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. Marine mammal communications would not likely be masked appreciably by the acoustic signals given the directionality of the signals for most HRG survey equipment types planned for use (Table 2) and the brief period when an individual mammal is likely to be exposed.

Classic stress responses begin when an animal's central nervous system perceives a potential threat to its homeostasis. That perception triggers stress responses regardless of whether a stimulus actually threatens the animal; the mere perception of a threat is sufficient to trigger a stress response (Moberg 2000; Seyle 1950). Once an animal's central nervous system perceives a threat, it mounts a biological response or defense that consists of a combination of the four general biological defense responses: Behavioral responses, autonomic nervous system

responses, neuroendocrine responses, or immune responses. In the case of many stressors, an animal's first and sometimes most economical (in terms of biotic costs) response is behavioral avoidance of the potential stressor or avoidance of continued exposure to a stressor. An animal's second line of defense to stressors involves the sympathetic part of the autonomic nervous system and the classical ''fight or flight'' response which includes the cardiovascular system, the gastrointestinal system, the exocrine glands, and the adrenal medulla to produce changes in heart rate, blood pressure, and gastrointestinal activity that humans commonly associate with ''stress.'' These responses have a relatively short duration and may or may not have significant long-term effect on an animal's welfare. An animal's third line of defense to stressors involves its neuroendocrine systems; the system that has received the most study has been the hypothalamus-pituitary-adrenal system (also known as the HPA axis in mammals). Unlike stress responses associated with the autonomic nervous system, virtually all neuro-endocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction (Moberg 1987; Rivier 1995), reduced immune competence (Blecha 2000), and behavioral disturbance. Increases in the circulation of glucocorticosteroids (cortisol, corticosterone, and aldosterone in marine mammals; see Romano *et al.,* 2004) have been long been equated with stress. The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and distress is the biotic cost of the response. In general, there are few data on the potential for strong, anthropogenic underwater sounds to cause non-auditory physical effects in marine mammals. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.,* 2007). There is currently no definitive evidence that any of these effects occur even for marine mammals in close proximity to an anthropogenic sound source. In addition, marine mammals that show behavioral avoidance of survey vessels and related sound sources are unlikely to incur non-auditory impairment or other physical effects. NMFS does not expect that the generally short-term, intermittent, and transitory HRG and geotechnical survey activities would create conditions of long-term, continuous noise and chronic acoustic exposure leading to long-term physiological stress responses in marine mammals.

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, and zooplankton) (*i.e.,* effects to marine mammal habitat). Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. The most likely impacts (if any) for most prey species in a given area would be temporary avoidance of the area. Surveys using active acoustic sound sources move through an area, limiting exposure to multiple pulses. In all cases, sound levels would return to ambient once a survey ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly. Finally, the HRG survey equipment will not have significant impacts to the seafloor and does not represent a source of pollution.

Vessel Strike

Vessel collisions with marine mammals, or ship strikes, can result in death or serious injury of the animal. These interactions are typically associated with large whales, which are less maneuverable than are smaller cetaceans or pinnipeds in relation to large vessels. Ship strikes generally involve commercial shipping vessels, which are generally larger and of which there is much more traffic in the ocean than geophysical survey vessels. Jensen and Silber (2004) summarized ship strikes of large whales worldwide from 1975–2003 and found that most collisions occurred in the open ocean and involved large vessels (*e.g.,* commercial shipping). For vessels used in geophysical survey activities, vessel speed while towing gear is typically only 4–5 knots. At these speeds, both the possibility of striking a marine mammal and the possibility of a strike resulting in serious injury or mortality are so low as to be discountable. At average transit speed for geophysical survey vessels, the probability of serious injury or mortality resulting from a strike is less than 50 percent. However, the likelihood of a strike actually happening is again low given the smaller size of these vessels and generally slower speeds. Notably in the Jensen and Silber study, no strike incidents were reported for geophysical survey vessels during that time period.

The potential effects of NEETMA's specified survey activity are expected to be limited to Level B behavioral harassment. No permanent or temporary auditory effects, or significant impacts to marine mammal habitat, including prey, are expected.

Marine Mammal Habitat

The HRG survey equipment will not contact the seafloor and does not represent a source of pollution. As the HRG survey equipment introduces noise to the marine environment, there is the potential for it to result in avoidance of the area around the HRG survey activities on the part of marine mammal prey. Any avoidance of the area on the part of marine mammal prey would be expected to be short term and temporary.

Because of the temporary nature of the disturbance, and the availability of similar habitat and resources (*e.g.,* prey species) in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. Impacts on marine mammal habitat from the proposed activities will be temporary, insignificant, and discountable.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to noise from certain HRG acoustic sources. Based primarily on the characteristics of the signals produced by the acoustic sources planned for use, Level A harassment is neither anticipated (even absent mitigation), nor proposed to be

authorized. Consideration of the anticipated effectiveness of the measures (*i.e.,* exclusion zones and shutdown measures), discussed in detail below in the Proposed Mitigation section, further strengthens the conclusion that Level A harassment is not a reasonably anticipated outcome of the survey activity. As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

NMFS uses acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007; Ellison *et al.,* 2012). NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals may be behaviorally harassed (*i.e.,* Level B harassment) when exposed to underwater anthropogenic noise above received levels of 160 dB re 1 µPa (rms) for the impulsive sources (*i.e.,* boomers, sparkers) and non-impulsive, intermittent sources (*e.g.,* CHIRP SBPs) evaluated here for NEETMA's proposed activity.

Level A Harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). For more information, see NMFS' 2018 Technical Guidance, which may be accessed at *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

NEETMA's proposed activity includes the use of impulsive (*i.e.,* sparkers and boomers) and non-impulsive, intermittent (*e.g.,* CHIRP SBP) sources. These can be found in Table 2.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

NMFS has developed a user-friendly methodology for estimating the extent of the Level B harassment isopleths associated with relevant HRG survey equipment (NMFS, 2020). This methodology incorporates frequency and directionality to refine estimated ensonified zones. For acoustic sources that operate with different beamwidths, the maximum beamwidth was used, and the lowest frequency of the source was used when calculating the frequency-dependent absorption coefficient.

NMFS considers the data provided by Crocker and Fratantonio (2016) to represent the best available information on source levels associated with HRG equipment and, therefore, recommends that source levels provided by Crocker and Fratantonio (2016) be incorporated in the method described above to estimate isopleth distances to harassment thresholds. In cases when the source level for a specific type of HRG equipment is not provided in Crocker and Fratantonio (2016), NMFS recommends that either the source levels provided by the manufacturer be used, or, in instances where source levels provided by the manufacturer are unavailable or unreliable, a proxy from Crocker and Fratantonio (2016) be used instead. Table 2 shows the HRG equipment types that may be used during the proposed surveys and the source levels associated with those HRG equipment types.

Results of modeling using the methodology described above indicated that, of the HRG survey equipment planned for use by NEETMA that has the potential to result in Level B harassment of marine mammals, the Applied Acoustics Dura-Spark UHD and GeoMarine Geo-Source sparkers would produce the largest Level B harassment isopleth (141 m). Estimated Level B harassment isopleths for all sources evaluated here, including the sparkers, are provided in Table 5. Although NEETMA does not expect to use sparker sources on all planned survey days, it proposes to assume for purposes of analysis that the sparker would be used on all survey days. This is a conservative approach, as the actual sources used on individual survey days may produce smaller harassment distances.

TABLE 5—DISTANCES TO LEVEL B HARASSMENT THRESHOLD

[160 dB rms]

Equipment category	HRG equipment	Distance to level B harassment threshold in meters (m)
Shallow SBPs	ET 216 CHIRP	9
	ET 424 CHIRP	4
	GeoPulse 5430	21
	TB CHIRP III	48
Medium SBPs	AA, triple plate S-Boom (700–1,000 J)	34
	AA, Dura-spark UHD (500 J/400 tip	141

TABLE 5—DISTANCES TO LEVEL B HARASSMENT THRESHOLD—Continued

[160 dB rms]

Equipment category	HRG equipment	Distance to level B harassment threshold in meters (m)
	AA, Dura-spark UHD 400+400	141
	GeoMarine Geo Spark 2000 (400 tip)	141

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

Habitat-based density models produced by the Duke University Marine Geospatial Ecology Laboratory and the Marine-life Data and Analysis Team, based on the best available marine mammal data from 1992–201 obtained in a collaboration between Duke University, the Northeast Regional Planning Body, the University of North Carolina Wilmington, the Virginia Aquarium and Marine Science Center, and NOAA (Roberts *et al.,* 2016a; Curtice *et al.,* 2018), represent the best available information regarding marine mammal densities in the survey area. More recently, these data have been updated with new modeling results and include density estimates for pinnipeds (Roberts *et al.,* 2016b, 2017, 2018).

The density data presented by Roberts *et al.* (2016b, 2017, 2018, 2020) incorporates aerial and shipboard line-transect survey data from NMFS and other organizations and incorporates data from eight physiographic and 16 dynamic oceanographic and biological covariates, and controls for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting. These density models were originally developed for all cetacean taxa in the U.S. Atlantic (Roberts *et al.,* 2016a). In subsequent years, certain models have been updated based on additional data as well as certain methodological improvements. More information is available online at *https://seamap.env.duke.edu/models/Duke/EC/*. Marine mammal density estimates in the survey area (animals/km^2) were obtained using the most recent model results for all taxa (Roberts *et al.,* 2016b, 2017, 2018, 2020). The updated models incorporate additional sighting data, including sightings from NOAA's Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys.

For the exposure analysis, marine mammal density data from Roberts *et al.* (2016a; 2016b; 2017; 2018; 2020; 2021a; 2021b) were mapped for the survey area using a geographic information system (GIS). NEETMA used all 10 x 10 km (6.2 x 6.2 mile) grid cells (5 x 5 km (3.1 x 3.1 mile) for the North Atlantic right whale) where the centroid was within each survey area in developing estimated density values for each species. For data in which the Roberts *et al.* data does not provide outputs at the species level (*i.e.,* pilot whale *spp.* and pinnipeds) the single annual density was used. For all other species, the monthly densities were used to yield the average annual density. Bottlenose dolphin density estimates were also divided based on the specified stock.

In the Roberts *et al.* (2016b, 2017, 2018) models, species-specific delineations were not made for some marine mammals, including some pinniped species' (harbor seal and gray seal) and for pilot whale *spp.* (long-finned and short-finned). For pilot whales, both species are known to share similar habitat in the project area, feed on similar prey, and have overlapping distributions (Mintzer *et al.,* 2008; Rone and Pace, 2012). Hayes *et al.* (2017) noted a particular overlap between the two species between New Jersey and George's Bank. Furthermore, due to their similar appearances at sea and difficulty in distinguishing species-specific characteristics, observers are likely to combine sightings of pilot whales (Waring, 1993; Rone and Pace, 2012; Stepanuk *et al.,* 2018).

Regarding the pinniped species, because the seasonality, feeding preferences, and habitat use by gray seals often overlaps with that of harbor seals in the survey areas, it was assumed that modeled takes of seals could occur to either of the respective species.

As discussed in the application, the single annual density for each marine mammal group (pilot whale *spp.* and pinnipeds) was applied and the results were divided between each species, resulting in an equal split.

For the bottlenose dolphin densities, Roberts *et al.* (2016b, 2017, 2018) does not differentiate by stock. The Western North Atlantic northern migratory coastal stock is generally expected to occur only in coastal waters from the shoreline to approximately the 20-m (65-ft) isobath (Hayes *et al.,* 2018). Both of these stocks have the potential to occur in the Northern and Southern survey areas. To account for the potential for mixed stocks within the survey areas, the densities of the two stocks were apportioned based on the 20-m isobaths contour. Any grid cells in the Roberts *et al.* data that feel entirely inshore of the 20-m isobaths were assigned to the coastal migratory stock. Any grid cells that fell outside this 20-m isobaths were apportioned to the offshore stock.

Densities from both of the survey sites were averaged annually to provide a density estimate for each species (Table 6). Please see Table 6 for density values used in the exposure estimation process. Additional data regarding average group sizes from survey effort in the region was considered to ensure adequate take estimates are evaluated.

TABLE 6—MAXIMUM SEASONAL MARINE MAMMAL DENSITIES (NUMBER OF ANIMALS PER 100 KM^2) IN THE NORTHERN AND SOUTHERN SURVEY AREAS

Species groups	Marine mammal species	Stock	Mean annual density (number of animals/100km^2) [a]	
			Northern survey area	Southern survey area
Cetaceans	North Atlantic right whale	Western North Atlantic	0.169	0.102
	Fin whale	Western North Atlantic	0.154	0.058
	Sperm whale	North Atlantic	0.017	0.002
	Humpback whale	Gulf of Maine	0.042	0.040
	Common minke whale	Canadian East Coast	0.044	0.010
	Risso's dolphin	Western North Atlantic	0.014	0.001
	Long-finned pilot whale	Western North Atlantic	0.108	0.005
	Short-finned pilot whale	Western North Atlantic	0.108	0.005
	Atlantic white-sided dolphin	Western North Atlantic	0.836	0.092
	Common dolphin (short-beaked)	Western North Atlantic	5.692	0.739
	Common bottlenose dolphin	Western North Atlantic—Offshore	2.616	8.158
		Western North Atlantic—Coastal Migratory.	14.203	33.409
	Atlantic spotted dolphin	Western North Atlantic	0.129	0.004
	Harbor porpoise	Gulf of Maine/Bay of Fundy	3.012	0.874
Pinnipeds	Harbor seal	Western North Atlantic	1.690	1.226
	Gray seal	Western North Atlantic	1.690	1.226

[a] All density data was derived from Roberts *et al.* (2016a, 2016b, 2017, 2018, 2020, 2021a, and 2021b)

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in harassment, radial distances to predicted isopleths corresponding to Level B harassment thresholds are calculated, as described above. The maximum distance (*i.e.,* 141-m distance associated with the Medium SBPs) to the Level B harassment criterion and the estimated distance traveled per day by a given survey vessel (*i.e.,* 62-km (38.5-mi)) are then used to calculate the daily ensonified area, or zone of influence (ZOI) around the survey vessel.

NEETMA estimates that proposed surveys will achieve a maximum daily track line distance of 62 km per day (24-hour period) during proposed HRG surveys. This distance accounts for the vessel traveling at approximately 4-knots and accounts for non-active survey periods. Based on the maximum estimated distance to the Level B harassment threshold of 141-m (refer back to Table 5) and the maximum estimated daily track line distance of 62-km across both survey sites, an area of 5,183.97-km^2 would be ensonified to the Level B harassment threshold during NEETMA's proposed surveys (Table 7) based on the following formula:

$$Mobile\ Source\ ZOI = (Distance/day \times 2r) + \pi r^2$$

Where:

Distance/day = the maximum distance a survey vessel could travel in a 24-hour period; and

r = the maximum radial distance from a given sound source to the NOAA Level B harassment thresholds.

TABLE 7—ZOI FOR EACH TYPE OF REPRESENTATIVE HRG SURVEY EQUIPMENT

Equipment type	Largest harassment isopleth in km (m); r	Distance/ day in km	ZOI (km^2)
Shallow SBP	0.048 (48)	62	5.98
Medium SBP (sparker)	0.141 (141)		17.61

These calculated ZOIs were than input to yield the total ensonified area per day (in km^2), as shown in Table 8 below.

TABLE 8—HRG SURVEY AREA DISTANCES FOR NEETMA'S PROPOSED PROJECT

HRG survey equipment type	Specific equipment used			Largest harassment isopleth; r (km)	Survey distances per day (km)[1]	Calculated ZOI per day (km^2)
Shallow SBP	TB CHIRP III			0.048	62	5.98
Medium (SBP)	AA, Dura-spark UHD (500 J/400 tip).	AA, Dura-spark UHD 400+400.	GeoMarine Geo Spark 2000 (400 tip).	0.141		17.61

[1] Assumes 24-hours of survey activity during the proposed project.

As described above, this is a conservative estimate as it assumes the HRG source that results in the greatest isopleth distance to the Level B harassment threshold would be operated at all times during the entire survey, which may not ultimately occur.

The number of marine mammals expected to be incidentally taken per day is then calculated by estimating the number of each species predicted to occur within the daily ensonified area (animals/km^2), incorporating the maximum seasonal estimated marine mammal densities as described above. Estimated numbers of each species taken per day across both survey sites are then multiplied by the total number of survey days (*i.e.,* 320). The product is then rounded, to generate an estimate of the total number of instances of harassment expected for each species over the duration of the survey. A summary of this method is illustrated in the following formula with the resulting proposed take of marine mammals is shown below in Table 11:

$$Estimated\ Take = D \times ZOI \times \#\ of\ days$$

Where:

D = average species density (per km^2); and
ZOI = maximum daily ensonified area to relevant thresholds.

TABLE 11—TOTAL ESTIMATED TAKES BY LEVEL B HARASSMENT AND PERCENT OF POPULATION/STOCK PROPOSED FOR NEETMA'S PROJECT

Marine mammal species	Stock	Calculated Level B take		Proposed Level B take	
		Northern survey area	Southern survey area	Proposed [a]	% stock [c]
North Atlantic right whale	Western North Atlantic	7.40	0.83	8	2.17
Fin whale	Western North Atlantic	6.73	0.47	7	0.10
Sperm whale	North Atlantic	0.73	0.02	3	0.07
Humpback whale	Gulf of Maine	1.83	0.33	[b] 3 (6)	[b] 0.21 (0.43)
Common minke whale	Canadian East Coast	1.92	0.08	2	0.01
Risso's dolphin	Western North Atlantic	0.62	0.01	30	0.09
Long-finned pilot whale	Western North Atlantic	4.72	0.04	20	0.05
Short-finned pilot whale	Western North Atlantic	4.72	0.04	20	0.07
Atlantic white-sided dolphin	Western North Atlantic	36.52	0.76	37	0.04
Common dolphin (short-beaked)	Western North Atlantic	248.52	6.04	255	0.15
Common bottlenose dolphin	Western North Atlantic—Offshore	53.88	9.27	63	0.10
	Western North Atlantic—Coastal Migratory.	325.25	235.27	561	8.45
Atlantic spotted dolphin	Western North Atlantic	5.61	0.03	100	0.25
Harbor porpoise	Gulf of Maine/Bay of Fundy	131.51	7.15	139	0.15
Harbor seal	Western North Atlantic	73.77	10.02	84	0.14
Gray seal	Western North Atlantic	73.77	10.02	84	0.31

[a] All of these values were requested by NEETMA, with exception for the value in parenthesis found for humpback whales.
[b] The values in parenthesis were a proposed adjustment by NMFS based on a proposed adjustment to account for higher recorded occurrences of humpback whales in the New York Bight area (see King *et al.,* 2021).
[c] Calculated percentages of population/stock were based on the population estimates (Nest) found in the NMFS's draft 2021 U.S. Atlantic and Gulf of Mexico Marine Mammal Stock Assessment on NMFS's website (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports*).

Adjustments have been made for sperm whales (Barkaszi and Kelly, 2019), Risso's dolphin (Baird *et al.,* 1991; Barkaszi and Kelly, 2019), pilot whales *spp.*(CETAP, 1982), and Atlantic spotted dolphins (Jefferson *et al.,* 2008) based on typical group sizes due to estimated takes lower than the predicted group size. The take numbers shown in Table 11 represent those originally calculated and requested by NEETMA with minor modifications proposed by NMFS for one species.

Based on recent information from King *et al.* (2021) that demonstrated that the humpback whale is commonly sighted along the New York Bight area, NMFS determined that the humpback whale take request may be too low given the occurrence of animals near the survey area. Because of this, NMFS proposes to increase the requested take to account for underestimates to the actual occurrence of this species within the density data.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

Mitigation for Marine Mammals and Their Habitat

NMFS proposes the following mitigation measures be implemented during NEETMA's proposed marine site characterization surveys. Pursuant to section 7 of the ESA, NEETMA would also be required to adhere to relevant Project Design Criteria (PDC) of the NMFS' Greater Atlantic Regional Fisheries Office (GARFO) programmatic consultation (specifically PDCs 4, 5, and 7) regarding geophysical surveys along the U.S. Atlantic coast (*https://www.fisheries.noaa.gov/new-england-mid-atlantic/consultations/section-7-take-reporting-programmatics-greater-atlantic#offshore-wind-site-assessment-and-site-characterization-activities-programmatic-consultation*).

Marine Mammal Exclusion Zones and Harassment Zones

Marine mammal exclusion zones (EZ) would be established around the HRG survey equipment and monitored by NMFS-approved protected species observers (PSOs):

- 500 m EZ for North Atlantic right whales during use of specified acoustic sources (sparkers, boomers, and non-parametric sub-bottom profilers).
- 100 m EZ for all other marine mammals, with certain exceptions specified below, during operation of impulsive acoustic sources (boomer and/or sparker).

If a marine mammal is detected approaching or entering the EZs during the HRG survey, the vessel operator would adhere to the shutdown procedures described below to minimize noise impacts on the animals. These stated requirements will be included in the site-specific training to be provided to the survey team.

Pre-Start Clearance

Marine mammal clearance zones would be established around the HRG survey equipment and monitored by protected species observers (PSOs):

- 500 m for all ESA-listed marine mammals; and,
- 100 m for all other marine mammals.

NEETMA would implement a 30-minute pre-start clearance period prior to the initiation of ramp-up of specified HRG equipment (see exception to this requirement in the Shutdown Procedures section below). During this period, clearance zones will be monitored by the PSOs, using the appropriate visual technology. Ramp-up may not be initiated if any marine mammal(s) is within its respective clearance zone. If a marine mammal is observed within a clearance zone during the pre-start clearance period, ramp-up may not begin until the animal(s) has been observed exiting its respective exclusion zone or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and seals, and 30 minutes for all other species).

Ramp-Up of Survey Equipment

A ramp-up procedure, involving a gradual increase in source level output, is required at all times as part of the activation of the acoustic source when technically feasible. The ramp-up procedure would be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the survey area by allowing them to vacate the area prior to the commencement of survey equipment operation at full power. Operators should ramp up sources to half power for 5 minutes and then proceed to full power.

Ramp-up activities will be delayed if a marine mammal(s) enters its respective exclusion zone. Ramp-up will continue if the animal has been observed exiting its respective exclusion zone or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and seals and 30 minutes for all other species).

Ramp-up may occur at times of poor visibility, including nighttime, if appropriate visual monitoring has occurred with no detections of marine mammals in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at night where operational planning cannot reasonably avoid such circumstances.

Shutdown Procedures

An immediate shutdown of the impulsive HRG survey equipment would be required if a marine mammal is sighted entering or within its respective exclusion zone. The vessel operator must comply immediately with any call for shutdown by the Lead PSO. Any disagreement between the Lead PSO and vessel operator should be discussed only after shutdown has occurred. Subsequent restart of the survey equipment can be initiated if the animal has been observed exiting its respective exclusion zone or until an additional time period has elapsed (*i.e.,* 15 minutes for harbor porpoise, 30 minutes for all other species).

If a species for which authorization has not been granted, or, a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the Level B harassment zone (refer back to Table 5), shutdown would occur.

If the acoustic source is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for less than 30 minutes, it may be activated again without ramp-up if PSOs have maintained constant observation and no detections of any marine mammal have occurred within the respective exclusion zones. If the acoustic source is shut down for a period longer than 30 minutes, then pre-clearance and ramp-up procedures will be initiated as described in the previous section.

The shutdown requirement would be waived for pinnipeds and for small delphinids of the following genera: *Delphinus, Lagenorhynchus, Stenella,* and *Tursiops*. Specifically, if a delphinid from the specified genera or a pinniped is visually detected approaching the vessel (*i.e.,* to bow ride) or towed equipment, shutdown is not required. Furthermore, if there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), PSOs must use best professional judgement in making the decision to call for a shutdown. Additionally, shutdown is required if a delphinid or pinniped is detected in the exclusion zone and belongs to a genus other than those specified.

Shutdown, pre-start clearance, and ramp-up procedures are not required during HRG survey operations using only non-impulsive sources (*e.g.,* echosounders) other than non-parametric sub-bottom profilers (*e.g.,* CHIRPs).

Vessel Strike Avoidance

NEETMA must adhere to the following measures except in the case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

- Vessel operators and crews must maintain a vigilant watch for all protected species and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any protected species. A visual observer aboard the vessel must monitor a vessel strike avoidance zone based on the appropriate separation distance around the vessel (distances stated below). Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members

responsible for these duties must be provided sufficient training to (1) distinguish protected species from other phenomena and (2) broadly to identify a marine mammal as a right whale, other whale (defined in this context as sperm whales or baleen whales other than right whales), or other marine mammal.

- Members of the monitoring team will consult NMFS North Atlantic right whale reporting system and WhaleAlert (*http://www.whalealert.org*), as able, for the presence of North Atlantic right whales throughout survey operations, and for the establishment of a DMA. If NMFS should establish a DMA in the survey area during the survey, the vessels will abide by speed restrictions in the DMA.
- All survey vessels, regardless of size, must observe a 10-knot speed restriction in specific areas designated by NMFS for the protection of North Atlantic right whales from vessel strikes including seasonal management areas (SMAs) and dynamic management areas (DMAs) when in effect;
- All vessels greater than or equal to 19.8 m in overall length operating from November 1 through April 30 will operate at speeds of 10 knots or less at all times;
- All vessels must reduce their speed to 10 knots or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel;
- All vessels must maintain a minimum separation distance of 500 m from right whales and other ESA-listed large whales;
- If a whale is observed but cannot be confirmed as a species other than a right whale or other ESA-listed large whale, the vessel operator must assume that it is a right whale and take appropriate action;
- All vessels must maintain a minimum separation distance of 100 m from non-ESA listed whales;
- All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.,* for animals that approach the vessel).
- When marine mammals are sighted while a vessel is underway, the vessel shall take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

Project-specific training will be conducted for all vessel crew prior to the start of a survey and during any changes in crew such that all survey personnel are fully aware and understand the mitigation, monitoring, and reporting requirements. Prior to implementation with vessel crews, the training program will be provided to NMFS for review and approval. Confirmation of the training and understanding of the requirements will be documented on a training course log sheet. Signing the log sheet will certify that the crew member understands and will comply with the necessary requirements throughout the survey activities.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, we have preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Proposed Monitoring Measures

Visual monitoring will be performed by qualified, NMFS-approved PSOs, the resumes of whom will be provided to NMFS for review and approval prior to the start of survey activities. NEETMA would employ independent, dedicated, trained PSOs, meaning that the PSOs must 1) be employed by a third-party observer provider, 2) have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements (including brief alerts regarding maritime hazards), and 3) have successfully completed an approved PSO training course appropriate for their designated task. On a case-by-case basis, non-independent observers may be approved by NMFS for limited, specific duties in support of approved, independent PSOs on smaller vessels with limited crew capacity operating in nearshore waters. Section 5 of the draft IHA contains further details regarding PSO approval.

The PSOs will be responsible for monitoring the waters surrounding each survey vessel to the farthest extent permitted by sighting conditions, including exclusion zones, during all HRG survey operations. PSOs will visually monitor and identify marine mammals, including those approaching or entering the established exclusion zones during survey activities. It will be the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate the action(s) that are necessary to ensure mitigation and

monitoring requirements are implemented as appropriate.

During all HRG survey operations (*e.g.,* any day on which use of an HRG source is planned to occur), a minimum of one PSO must be on duty during daylight operations on each survey vessel, conducting visual observations at all times on all active survey vessels during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). Two PSOs will be on watch during nighttime operations. The PSO(s) would ensure 360° visual coverage around the vessel from the most appropriate observation posts and would conduct visual observations using binoculars and/or night vision goggles and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. PSOs may be on watch for a maximum of 4 consecutive hours followed by a break of at least 2 hours between watches and may conduct a maximum of 12 hours of observation per 24-hr period. In cases where multiple vessels are surveying concurrently, any observations of marine mammals would be communicated to PSOs on all nearby survey vessels.

PSOs must be equipped with binoculars and have the ability to estimate distance and bearing to detect marine mammals, particularly in proximity to exclusion zones. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the sighting and monitoring of marine mammals. During nighttime operations, night-vision goggles with thermal clip-ons and infrared technology would be used. Position data would be recorded using hand-held or vessel GPS units for each sighting.

During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), to the maximum extent practicable, PSOs would also conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the active acoustic sources. Any observations of marine mammals by crew members aboard any vessel associated with the survey would be relayed to the PSO team. Data on all PSO observations would be recorded based on standard PSO collection requirements. This would include dates, times, and locations of survey operations; dates and times of observations, location and weather; details of marine mammal sightings (*e.g.,* species, numbers, behavior); and details of any observed marine mammal behavior that occurs (*e.g.,* noted behavioral disturbances).

Proposed Reporting Measures

Within 90 days after completion of survey activities or expiration of this IHA, whichever comes sooner, a draft report will be provided to NMFS that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, summarizes the number of marine mammals observed during survey activities (by species, when known), summarizes the mitigation actions taken during surveys (including what type of mitigation and the species and number of animals that prompted the mitigation action, when known), and provides an interpretation of the results and effectiveness of all mitigation and monitoring. A final report must be submitted within 30 days following resolution of any comments on the draft report. All draft and final marine mammal and acoustic monitoring reports must be submitted to *PR.ITP.MonitoringReports@noaa.gov* and *ITP.Potlock@noaa.gov*. The report must contain at minimum, the following:

- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort begins and ends;
- Vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including wind speed and direction, Beaufort sea state, Beaufort wind force, swell height, weather conditions, cloud cover, sun glare, and overall visibility to the horizon;
- Factors that may be contributing to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions); and
- Survey activity information, such as type of survey equipment in operation, acoustic source power output while in operation, and any other notes of significance (*i.e.,* pre-start clearance survey, ramp-up, shutdown, end of operations, etc.).

If a marine mammal is sighted, the following information should be recorded:

- Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Vessel location at time of sighting;
- Water depth;
- Direction of vessel's travel (compass direction);
- Direction of animal's travel relative to the vessel;
- Pace of the animal;
- Estimated distance to the animal and its heading relative to vessel at initial sighting;
- Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified); also note the composition of the group if there is a mix of species;
- Estimated number of animals (high/low/best);
- Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
- Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- Detailed behavior observations (*e.g.,* number of blows, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
- Animal's closest point of approach and/or closest distance from the center point of the acoustic source;
- Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, data acquisition, other); and
- Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up, speed or course alteration, etc.) and time and location of the action.

If a North Atlantic right whale is observed at any time by PSOs or personnel on any project vessels, during surveys or during vessel transit, NEETMA must immediately report sighting information to the NMFS North Atlantic Right Whale Sighting Advisory System: (866) 755–6622. North Atlantic right whale sightings in any location may also be reported to the U.S. Coast Guard via Channel 16.

In the event that NEETMA personnel discover an injured or dead marine mammal, NEETMA will report the incident to the NMFS Office of Protected Resources (OPR) and the NMFS New England/Mid-Atlantic Stranding Coordinator (978–282–8478 or 978–281–9291) as soon as feasible. The report would include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

In the unanticipated event of a ship strike of a marine mammal by any vessel involved in the activities covered by the IHA, NEETMA would report the incident to the NMFS OPR and the NMFS New England/Mid-Atlantic Stranding Coordinator (978–282–8478 or 978–281–9291) as soon as feasible. The report would include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Species identification (if known) or description of the animal(s) involved;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Estimated size and length of animal that was struck;
- Description of the behavior of the marine mammal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. NMFS also assesses the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, our analysis applies to all the species listed in Table 3 given that NMFS expects the anticipated effects of the proposed survey to be similar in nature. Where there are meaningful differences between species or stocks—as is the case of the North Atlantic right whale—they are included as separate subsections below. NMFS does not anticipate that serious injury or mortality would occur as a result from HRG surveys, even in the absence of mitigation, and no serious injury or mortality is proposed to be authorized. As discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, non-auditory physical effects and vessel strike are not expected to occur. NMFS expects that all potential takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity was occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007). Even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. As described above, Level A harassment is not expected to occur given the nature of the operations and the estimated size of the Level A harassment zones.

In addition to being temporary, the maximum expected harassment zone around a survey vessel is 141 m. Although this distance is assumed for all survey activities in estimating take numbers proposed for authorization and evaluated here, in reality much of the survey activity would involve use of non-impulsive acoustic sources with a reduced acoustic harassment zone of 48 m, producing expected effects of particularly low severity. Therefore, the ensonified area surrounding each vessel is relatively small compared to the overall distribution of the animals in the area and their use of the habitat. Feeding behavior is not likely to be significantly impacted as prey species are mobile and are broadly distributed throughout the survey area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance and the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

There are no rookeries, mating or calving grounds known to be biologically important to marine mammals within the proposed survey area and there are no feeding areas known to be biologically important to marine mammals within the proposed survey area. There is no designated critical habitat for any ESA-listed marine mammals in the proposed survey area.

North Atlantic Right Whales

The status of the North Atlantic right whale population is of heightened concern and, therefore, merits additional analysis. As noted previously, elevated North Atlantic right whale mortalities began in June 2017 and there is an active UME. Overall, preliminary findings support human interactions, specifically vessel strikes and entanglements, as the cause of death for the majority of right whales. As noted previously, the proposed survey area overlaps a migratory corridor BIA for North Atlantic right whales. Due to the fact that the proposed survey activities are temporary and the spatial extent of sound produced by the survey would be very small relative to the spatial extent of the available migratory habitat in the

BIA, right whale migration is not expected to be impacted by the proposed survey. Given the relatively small size of the ensonified area, it is unlikely that prey availability would be adversely affected by HRG survey operations. Required vessel strike avoidance measures will also decrease risk of ship strike during migration; no ship strike is expected to occur during NEETMA's proposed activities. Additionally, only very limited take by Level B harassment of North Atlantic right whales has been requested and is being proposed for authorization by NMFS as HRG survey operations are required to maintain a 500 m EZ and shutdown if a North Atlantic right whale is sighted at or within the EZ. The 500 m shutdown zone for right whales is conservative, considering the Level B harassment isopleth for the most impactful acoustic source (*i.e.,* sparker) is estimated to be 141 m, and thereby minimizes the potential for behavioral harassment of this species. As noted previously, Level A harassment is not expected due to the small PTS zones associated with HRG equipment types proposed for use. NMFS does not anticipate North Atlantic right whales takes that would result from NEETMA's proposed activities would impact annual rates of recruitment or survival. Thus, any takes that occur would not result in population level impacts.

Other Marine Mammal Species With Active UMEs

As noted previously, there are several active UMEs occurring in the vicinity of NEETMA's proposed survey area. Elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately half had evidence of human interaction (ship strike or entanglement). The UME does not yet provide cause for concern regarding population-level impacts. Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or DPS) remains stable at approximately 12,000 individuals.

Beginning in January 2017, elevated minke whale strandings have occurred along the Atlantic coast from Maine through South Carolina, with highest numbers in Massachusetts, Maine, and New York. This event does not provide cause for concern regarding population level impacts, as the likely population abundance is greater than 20,000 whales.

The required mitigation measures are expected to reduce the number and/or severity of proposed takes for all species listed in Table 3, including those with active UMEs, to the level of least practicable adverse impact. In particular they would provide animals the opportunity to move away from the sound source throughout the survey area before HRG survey equipment reaches full energy, thus preventing them from being exposed to sound levels that have the potential to cause injury (Level A harassment) or more severe Level B harassment. No Level A harassment is anticipated, even in the absence of mitigation measures, or proposed for authorization.

NMFS expects that takes would be in the form of short-term Level B behavioral harassment by way of brief startling reactions and/or temporary vacating of the area, or decreased foraging (if such activity was occurring)—reactions that (at the scale and intensity anticipated here) are considered to be of low severity, with no lasting biological consequences. Since both the sources and marine mammals are mobile, animals would only be exposed briefly to a small ensonified area that might result in take. Additionally, required mitigation measures would further reduce exposure to sound that could result in more severe behavioral harassment.

Biologically Important Areas for Other Species

As previously discussed, impacts from the proposed project are expected to be localized to the specific area of activity and only during periods of time where NEETMA's acoustic sources are active. While areas of biological importance to fin whales, humpback whales, and harbor seals can be found off the coast of New Jersey and New York, NMFS does not expect this proposed action to affect these areas. These important areas are found outside of the range of this survey area, as is the case with fin whales and humpback whales (BIAs found further north), and, therefore, not expected to be impacted by NEETMA's proposed survey activities.

There are three major haul-out sites exist for harbor seals along New Jersey, including at Great Bay, Sand Hook, and Barnegat Inlet (CWFNJ, 2015). As hauled out seals would be out of the water, no in-water effects are expected.

Preliminary Determinations

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality or serious injury is anticipated or proposed for authorization;
- No Level A harassment is anticipated, even in the absence of mitigation measures, or proposed for authorization;
- Foraging success is not likely to be significantly impacted as effects on species that serve as prey species for marine mammals from the survey are expected to be minimal;
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the planned survey to avoid exposure to sounds from the activity;
- Take is anticipated to be by Level B behavioral harassment only, consisting of brief startling reactions and/or temporary avoidance of the survey area;
- While the survey area is within areas noted as a migratory BIA for North Atlantic right whales, the activities would occur in such a comparatively small area such that any avoidance of the survey area due to activities would not affect migration. In addition, mitigation measures require shutdown at 500 m (almost four times the size of the Level B harassment isopleth (141 m)), which minimizes the effects of the take on the species; and,
- The proposed mitigation measures, including visual monitoring and shutdowns, are expected to minimize potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed mitigation, monitoring, and reporting measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be

taken is fewer than one third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

NMFS proposes to authorize incidental take of 15 marine mammal species (with 16 managed stocks). The total amount of takes proposed for authorization relative to the best available population abundance is less than 8.5 percent for all stocks which NMFS preliminarily finds are small numbers of marine mammals relative to the estimated overall population abundances for those stocks. Refer back to Table 3.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS Office of Protected Resources (OPR) consults internally whenever we propose to authorize take for endangered or threatened species. NMFS is authorizing the incidental take of four species of marine mammals which are listed under the ESA, including the North Atlantic right, fin, and sperm whale, and has determined that these activities fall within the scope of activities analyzed 107 in GARFO's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to NEETMA for conducting high-resolution site characterization surveys off New Jersey for one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable*.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed marine site characterization surveys. We also request at this time comment on the potential Renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for Renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).
- The request for Renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: May 4, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB882]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Tugs Towing Drill Rig in Cook Inlet, Alaska

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

ACTION: Notice; proposed incidental harassment authorizations; request for comments on proposed authorizations.

SUMMARY: NMFS has received a request from Hilcorp Alaska LLC (Hilcorp) for authorization to take marine mammals incidental to tugboats towing a drill rig in Cook Inlet, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue two successive incidental harassment authorizations (IHAs) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than June 8, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief,

Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Written comments should be submitted via email to *ITP.Young@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Sara Young, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review its proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment. Accordingly, NMFS is preparing an Environmental Assessment (EA) to consider the environmental impacts associated with the issuance of the proposed IHAs. NMFS' EA will be made available at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* at the time of publication. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA requests.

Summary of Request

On January 13, 2022, NMFS received a request from Hilcorp for two IHAs to take marine mammals incidental to tugs towing a drill rig in Cook Inlet, Alaska. The application was deemed adequate and complete on March 8, 2022. Hilcorp's request is for take of small numbers of eleven species of marine mammals by Level B harassment only. Neither Hilcorp nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued Incidental Take Regulations (ITRs) to Hilcorp for a suite of oil and gas activities in Cook Inlet, Alaska (84 FR 37442; July 31, 2019) and issued three letters of authorization (LOAs) under those ITRs. The ITRs covered activities including: Two-dimensional (2D) and three-dimensional (3D) seismic surveys, geohazard surveys, vibratory sheet pile driving, and drilling of exploratory wells. On September 17, 2019, Cook Inletkeeper and the Center for Biological Diversity filed suit in the District of Alaska challenging NMFS's issuance of the ITRs and LOAs and supporting documents (the EA and Endangered Species Act (ESA) Biological Opinion). In a decision issued on March 30, 2021, the court ruled largely in NMFS's favor, but found a lack of adequate support in NMFS's record for the agency's determination that tug towing of drill rigs in connection with production activity will not cause take of beluga whales and remanded back to NMFS for further analysis of tug use under the MMPA, ESA, and NEPA. Hilcorp notified NMFS that all activities described in their initial ITR application (2018) and for which incidental take was authorized have already been completed or will not be completed in the remaining effective period of the ITRs. As a result, the only remaining activity to be analyzed is the use of tugs towing a jack-up rig. NMFS proposes to authorize incidental take from the tugs towing a jack-up rig through two sequential IHAs as the appropriate mechanism, given that there are no more activities occurring under the ITRs, no serious injury or mortality is expected, and Hilcorp's timing needs.

Description of Proposed Activity

Overview

Hilcorp Alaska, LLC (Hilcorp) plans to carry out activities that will occur over two separate one-year periods—from April 1, 2022 to March 31, 2023 (Year 1) and from April 1, 2023 to March 31, 2024 (Year 2). Hilcorp plans to use three ocean-going tugs to tow a jack-up rig in support of plugging and abandonment (P&A) of an existing well and to support production drilling at other locations in middle Cook Inlet and Trading Bay over the course of two years.

Dates and Duration

The schedule for Hilcorp's P&A and production drilling activities is provided in Table 1 below. The noise-producing rig-towing activities for which take is proposed would occur in between those activities, for approximately 16 days per year for Year 1 and Year 2.

TABLE 1—DATES AND DURATIONS OF PLANNED ACTIVITIES IN COOK INLET

Project type	Cook inlet region	Timing	Duration of activity * (days)
Year 1:			
Plug and Abandonment of Well 17589	Middle Cook Inlet	April–November	30
Production Drilling	Middle Cook Inlet Trading Bay	April–November	180
Year 2:			
Production Drilling	Middle Cook Inlet Trading Bay	April–November	180

* Duration is in reference to the supported activity that requires the jack-up rig to be in a specific location. It is not reflective of the duration or the number of days the jack-up rig is towed.

Specific Geographic Region

Hilcorp's proposed activities would take place in Cook Inlet, Alaska. For the purposes of this project, lower Cook Inlet refers to waters south of the East and West Forelands; middle Cook Inlet refers to waters north of the East and West Forelands and south of Threemile River on the west and Point Possession on the east; Trading Bay refers to waters from approximately the Granite Point Tank Farm on the north to the West Foreland on the south; and upper Cook Inlet refers to waters north and east of Beluga River on the west and Point Possession on the east. A map of the specific area in which Hilcorp plans to operate is provided in Figure 1 below.

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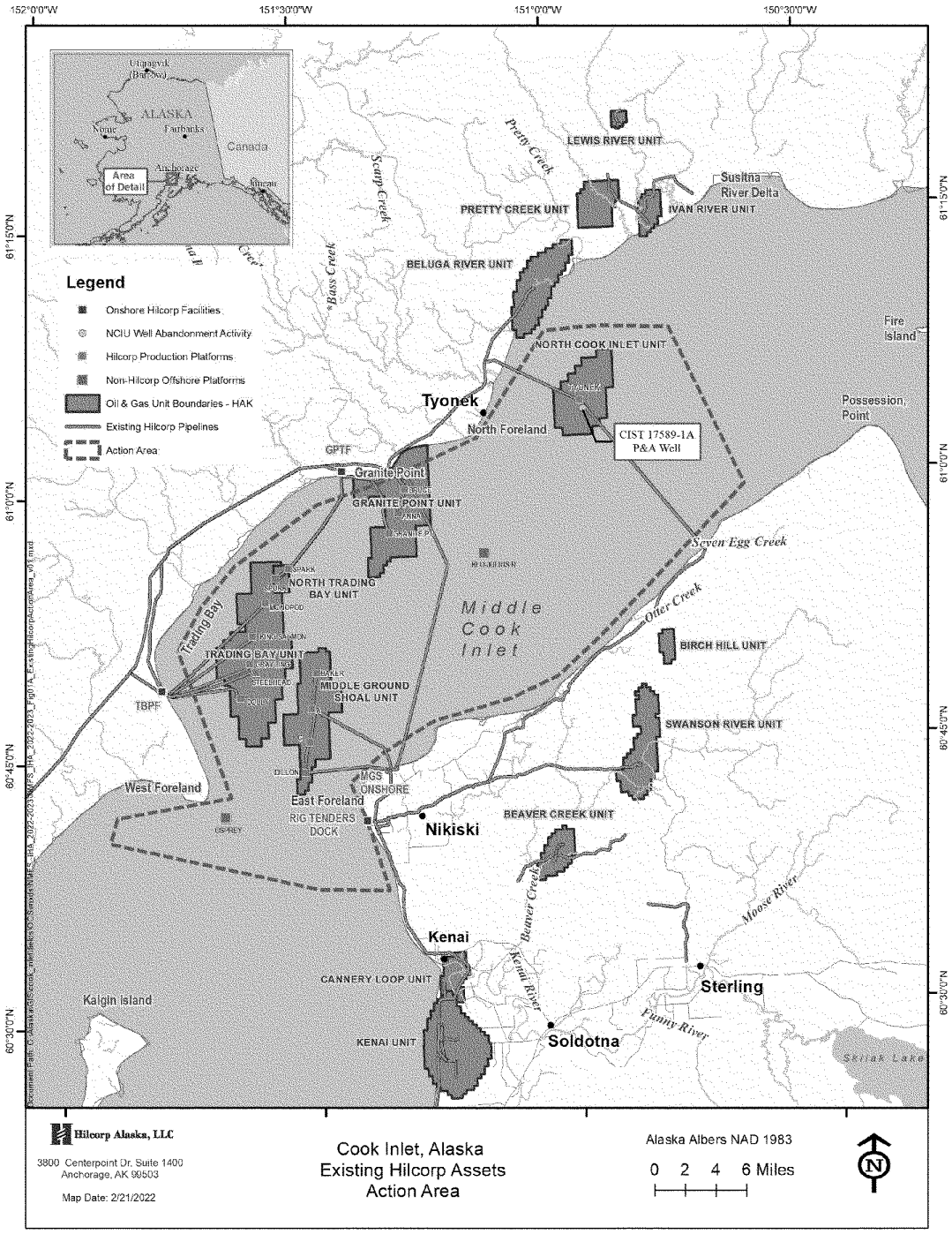

Figure 1. Map of Hilcorp's Proposed Activity Location

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Detailed Description of Specific Activity

Hilcorp proposes to use three tugs to pull and position a jack-up rig in support of well plugging and abandonment (P&A) and support of production drilling by using the rig as a temporary drilling platform. Hilcorp proposes to use the jack-up rig Spartan 151, or similar. A jack-up rig is a type of mobile offshore drill unit used in offshore oil and gas drilling activities. It is comprised of a buoyant mobile platform or hull with moveable legs that are adjusted to raise and lower the hull over the surface of the water. The Spartan 151 (or similar) will be towed via three ocean-going tugs. The horsepower (hp) of each of the three tugs used to tow the jack-up rig may range between 4,000 and 8,000. Three tugs are needed to safely and effectively pull the jack-up rig into the correct position where it can be temporarily secured to the seafloor. Specifications of the tugs anticipated for use are provided in Table 2 below. If these specific tugs are not available, the tugs contracted would be of similar size and power to those listed in Table 2.

TABLE 2—DESCRIPTION OF TUGS TOWING THE JACK-UP RIG

Vessel name	Specifications
M/V Bering Wind.	22-m length × 10-m breadth, 144 gross tonnage
M/V Anna T ...	32-m length × 11-m breadth, 160 gross tonnage
M/V Bob Franco.	37-m length × 11-m breadth, 196 gross tonnage

The amount of time the tugs are under load transiting, holding, and positioning the jack-up rig in Cook Inlet is tide-dependent. The power output of the tugs depends on whether the tugs are towing with or against the tide and can vary across a tide cycle as the current increases or decreases in speed over time. Hilcorp proposes to make every effort to transit with the tide (which requires lower power output) and minimize transit against the tide (which requires higher power output).

The jack-up rig will be mobilized and demobilized via towing by three ocean-going tugs from and to the Rig Tenders Dock in Nikiski, Alaska. A high slack tide is necessary for the tugs to approach close enough to shore to attach and mobilize the jack-up rig from the Rig Tenders Dock. Because Hilcorp's production platforms/well sites are north of the initial mobilization site, the tugs will begin their transit from Nikiski against an outgoing tide. To minimize transit time against the outgoing tide and reduce power output, the tugs will first tow the jack-up rig to a location near the Offshore Systems Kenai dock for approximately three hours, which provides protection from the fast outgoing tidal current. Protection from the outgoing tidal current will allow the tugs to expend less power holding the jack-up rig in position than they would if they continued to transit against the tide. The tugs will begin transiting north again when the tide changes to an incoming tide, which is about six hours after the high slack tide. Towing the jack-up rig northward with an incoming tide requires less than half power, generally only 20 to 30 percent of total power output (Durham 2021, pers. comm.).

A high slack tide is preferred to position the jack-up rig on an existing platform or well site. The relatively slow current and calm conditions at a slack tide enables the tugs to perform the fine movements necessary to safely position the jack-up rig within several feet of the platform. Positioning and securing the jack-up rig is generally performed at high slack tide rather than low slack tide to pin the legs down at an adequate height to ensure the hull of the jack-up rig remains above the water level of the subsequent incoming high tide. Because 12 hours elapse between each high slack tide, tugs are generally under load for those 12 hours, even if the towed distance is small, as high slack tides are preferred to both attach and detach the jack-up rig from the tugs. Once the tugs are on location with the jack-up rig at high slack tide (12 hours from the previous departure), there is a 1 to 2-hour window when the tide is slow enough for the tugs to initiate positioning the jack-up rig and pin the legs to the seafloor on location. The tugs are estimated to be under load, generally at half-power conditions or less, for up to 14 hours from the time of departure through the initial positioning attempt of the jack-up rig. If the first positioning attempt takes longer than anticipated, the increasing current speed prevents the tugs from safely positioning the jack-up rig on location. If the first positioning attempt is not successful, the jack-up rig will be pinned down at a nearby location and the tugs will be released from the jack-up rig and no longer under load. The tugs will remain nearby, generally floating with the current. Approximately an hour before the next high slack tide, the tugs will re-attach to the jack-up rig and reattempt positioning over a period of 2 to 3 hours. Positioning activities are generally at half power. If a third attempt is needed, the tugs would be under load holding or positioning the jack-up rig on a second day for up to 5 hours. The vast majority of the time, the jack-up rig can be successfully positioned over the platform in one or two attempts.

A location-to-location transport (*e.g.,* platform-to-platform) of a jack-up rig is conducted similarly to the mobilization from the Rig Tenders Dock described above with one main difference. In a location-to-location transport in middle Cook Inlet or Trading Bay, there is no harbor available for temporary staging to avoid transiting against the tide. Maintaining position of the jack-up rig against the tidal current can require more than half power (up to 90 percent power at the peak tidal outflow). However, greater than half power effort is only needed for short periods of time during the maximum tidal current, expected to be no more than three hours maximum. During a location-to-location transport, the tugs will transport the jack-up rig traveling with the tide in nearly all circumstances except in situations that threaten the safety of humans and/or infrastructure integrity. There may be a situation wherein the tugs pulling the jack-up rig begin transiting with the tide to their next location, miss the tide window to safely set the jack-up rig on the platform or pin it nearby, and so have to transport the jack-up rig against the tide to a safe harbor. Tugs may also need to transport the jack-up rig against the tide if large pieces of ice or extreme wind events threaten the stability of the jack-up rig on the platform.

Although the variability in power output from the tugs can range from an estimated 20 percent to 90 percent throughout the hours under load with the jack-up rig, as described above, the majority of the hours (spent transiting, holding, and positioning) occur at half power or less. See the Estimated Take section below for more detail on assumptions related to power output.

Year 1—For the first year of activity, Hilcorp proposes use of three tugs to pull the jack-up rig for plugging and abandonment (P&A) of Well 17589, which began in 2021 but was not completed due to equipment sourcing issues. Prior to pinning the jack-up rig legs to the seafloor, a multi-beam sonar may be used to ensure the seafloor is clear of debris that may impact the ability to pin down the legs of the platform. The multibeam echosounder emits high frequency (240 kilohertz [kHz]) energy in a fan-shaped pattern of equidistant or equiangular beam spacing. The multi-beam sonar operates at a frequency outside of marine mammal hearing range and is not addressed further in our analysis. After the rig is secure, divers enter the water and use hand tools to complete the P&A process. In addition to the hand tools, the divers will also use water jets to wash away debris and marine growth on the structure (*e.g.,* a CaviDyne CaviBlaster). Based on measurements conducted by Hilcorp during 2017 use of water jets, the source level for the CaviBlaster® was estimated as 176 decibels (dB) re 1 micropascal (µPa) root mean square (rms) with a Level B harassment threshold of 860 m, with most energy concentrated above 500 Hz with a dominant tone near 2 kHz. Hilcorp plans to put a protected species observer (PSO) on watch to monitor the full extent of the harassment zone and shutdown when an animal approaches the zone during water jet use. Because of this, Hilcorp is not requesting take associated with water jet use and it is not considered further in our analysis.

Hilcorp also plans to tug the jack-up rig to existing platforms in middle Cook Inlet and Trading Bay in support of production drilling activities from existing platforms and wellbores. Production drilling itself creates some small level of noise due to the use of

generators and other potentially noise-generating equipment. Furie Operating Alaska, LLC, performed detailed underwater acoustic measurements in the vicinity of the Spartan 151 in 2011 (Marine Acoustics Inc. 2011) northeast of Nikiski Bay in water depths of 24.4 to 27.4 m (80 to 90 ft). Primary sources of rig-based acoustic energy were identified as coming from the D399/D398 diesel engines, the PZ–10 mud pump, ventilation fans, and electrical generators. The source level of one of the loudest acoustic sources, the diesel engines, was estimated to be 137 dB re 1 µPa rms at 1 m in the 141 to 178 Hz frequency range. Based on this measured level, the 120 dB rms acoustic received level isopleth would be approximately 50 m away from where the energy enters the water (jack-up leg or drill riser). This small radius would overlap substantially with the physical footprint of the platform and other equipment, so Hilcorp is not requesting take for this activity and it is not considered further in our analysis. In support of these activities, helicopters and support vessels transit from the mainland to the production sites to mobilize personnel and supplies. Helicopters will fly at 1,500 ft or higher unless human safety is at risk or it is operationally impossible (*e.g.,* takeoff and landing points are so close together the aircraft cannot reach 1,500 ft). Vessel trips to and from the location of the jack-up rig are expected to increase by two trips per day above normal activity levels.

Year 2—For the second year of activity, Hilcorp does not plan to conduct P&A activities with the jack-up rig and will only be tugging the jack-up rig in support of production drilling activities.

The specific configuration of tugs towing the jack-up-rig as proposed by Hilcorp has not been analyzed previously. Hilcorp contracted JASCO Applied Sciences to conduct a sound source verification (SSV) of their tugs in operation in Cook Inlet during October 2021. This SSC measured tugs pulling the jack-up-rig at various power outputs. This SSV returned a source level of a source level of 167.3 dB re 1 µPa for the 20 percent power scenario and a source level of 205.9 dB re 1 µPa for the 85 percent power scenario. Assuming a linear scaling of tug power, a source level of 185 dB re 1 µPa was then calculated as a single point source level for three tugs operating at 50% power output. This is approximately five dB higher than the literature summary described below.

Hilcorp conducted a literature review of available source level data for tugs under load in varying power output scenarios. Table 3 below provides values of measured source levels for tugs varying from 2,000 to 8,2000 horsepower. For the purposes of this table, berthing activities could include tugs either pushing or pulling a load. The sound source levels appear correlated to speed and power output, with full power output and higher speeds generating more propeller cavitation and greater sound source levels than lower power output and lower speeds. Additional tug source levels are available from the literature but they are not specific to tugs under load but rather measured values for tugs during activities such as transiting, docking, and anchor pulling. For a summary of these additional tug values, see Table 7 in Hilcorp's application.

TABLE 3—LITERATURE VALUES OF MEASURED TUG SOURCE LEVELS

Vessel	Vessel length (m)	Speed (knots)	Activity	Source level @1 m (re: 1 µPa)	Horsepower	Reference
Eagle	32	9.6	Towing barge	173	6,770	Bassett *et al.* 2012.
Valor	30	8.4	Towing barge	168	2,400	
Lela Joy	24	4.9	Towing barge	172	2,000	
Pacific Eagle	28	8.2	Towing barge	165	2,000	
Shannon	30	9.3	Towing barge	171	2,000	
James T Quigg	30	7.9	Towing barge	167	2,000	
Island Scout	30	5.8	Towing barge	174	4,800	
Chief	34	11.4	Towing barge	174	8,200	
Lauren Foss	45	N/A	Berthing barge	167	8,200	Austin *et al.* 2013.
Seaspan Resolution	30	N/A	Berthing at half power	180	6,000	Roberts Bank Terminal 2 Technical Report 2014.
Seaspan Resolution	30	N/A	Berthing at full power	200	6,000	

The Roberts Bank Terminal 2 Technical Report (2014), although not in Cook Inlet, includes repeated measurements of the same tug operating under different speeds and loads. This allows for a comparison of source levels from the same vessel at half power versus full power, which is an important distinction for Hilcorp's activities, as a small fraction of the total time spent by tugs under load will be at greater than 50 percent power. The Seaspan Resolution's half-power berthing scenario has a sound source level of 180 dB re 1 µPa at 1 m. In addition, the Roberts Bank Report (2014) analyzed 650 tug transits under varying load and speed conditions and reported mean tug source levels of 179.3 dB re 1 µPa at 1 m, the 25th percentile was 179.0 dB re 1 µPa at 1 m, and 5th percentile source levels were 184.9 dB re 1 µPa at 1 m.

Based solely on the literature review, a source level of 180 dB for a tug under load would be appropriate. However, Hilcorp's use of a three tug configuration would increase the literature source level to approximately 185dB. As one or two tugs are primarily under load, the third tug sits off to the side. NMFS still considers these tugs to be simultaneous sources. When considered in conjunction with the additional tugs present in the configuration as well as the SSV conducted by JASCO for Hilcorp's specific configuration, a source level of 185 dB for tugs towing a jack-up rig was carried forward for analysis.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. Additional information

regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 4 lists all species or stocks for which take is expected and proposed to be authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow the Committee on Taxonomy (2021). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. 2020 SARs (*e.g.,* Muto *et al.* 2021). All values presented in Table 4 are the most recent available at the time of publication and are available in the 2020 SARs (Muto *et al.* 2021) and draft 2021 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 4—MARINE MAMMAL SPECIES OR STOCKS FOR WHICH TAKE IS EXPECTED AND PROPOSED TO BE AUTHORIZED

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern Pacific	-, -, N	26,960 (0.05, 25,849, 2016).	801	131
Family Balaenidae:						
Humpback whale	*Megaptera novaeangliae*	Western North Pacific	E, D, Y	1,107 (0.3, 865, 2006)	3	2.8
Minke whale	*Balaenoptera acutorostrata*	Alaska	-, -, N	N/A (see SAR, N/A, see SAR).	UND	0
Family Balaenopteridae (rorquals):						
Fin whale	*Balaenoptera physalus*	Northeastern Pacific	E, D, Y	see SAR (see SAR, see SAR, 2013).	see SAR	0.6
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Beluga whale	*Delphinapterus leucas*	Cook Inlet	E, D, Y	279 (0.061, 267, 2018)	see SAR	0
Killer whale	*Orcinus orca*	Alaska Resident	-, -, N	2,347 c (N/A, 2347, 2012).	24	1
Killer whale	*Orcinus orca*	Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	-, -, N	587 c (N/A, 587, 2012)	5.87	0.8
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Alaska	-, -, Y	31,046 (0.21, N/A, 1998)	UND	72
Dall's porpoise	*Phocoenoides dalli*	Alaska	-, -, N	see SAR (0.097, see SAR, 2015).	see SAR	37
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
Steller sea lion	*Eumetopias jubatus*	Western	E, D, Y	52,932 a (see SAR, 52,932, 2019).	318	254
California sea lion	*Zalophus californianus*	U.S	-, -, N	257,606 (N/A,233,515, 2014).	14011	>320
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Cook Inlet/Shelikof	-, -, N	28,411 (see SAR, 26,907, 2018).	807	107

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable depending on the methodology described in the stock assessment report (SAR) and the date of last available survey data. Where necessary, NMFS refers reader to the SAR for more detail.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual mortality and serious injury often cannot be determined precisely and is in some cases presented as a minimum value or range.

As indicated above, all 11 species (with 12 managed stocks) in Table 4 temporally and spatially co-occur with the activity to the degree that take could reasonably occur, and we have proposed authorizing it. In addition, the northern sea otter may be found in Cook Inlet, Alaska. However, sea otters are managed by the U.S. Fish and Wildlife Service and are not considered further in this document.

Gray Whale

The eastern North Pacific stock of gray whales occurring in Cook Inlet are likely migrating to summer feeding grounds in the Bering, Chukchi, and Beaufort seas, although some whales are known to feed near Kodiak Island (Carretta *et al.* 2014). Gray whales generally breed every two years during November and December while undertaking the southern migration (Jones and Swartz 2009). Gray whales have been reported feeding near Kodiak Island, in southeastern Alaska, and south along the Pacific Northwest (Allen and Angliss 2013). Most gray whales migrating through the Gulf of Alaska region are thought to take a coastal route and (Ferguson *et al.* 2015) delineated the migratory corridor biologically important area (BIA) boundaries based on the extent of the continental shelf.

Most gray whales calve and breed from late December to early February in protected waters along the western coast of Baja California, Mexico. In spring, the Eastern North Pacific stock of gray whales migrates ~8,000 km (5,000 mi) to feeding grounds in the Bering and Chukchi seas before returning to their wintering areas in the fall (Rice and Wolman 1971). Northward migration, primarily of individuals without calves, begins in February; some cow/calf pairs delay their departure from the calving area until well into April (Jones and Swartz 1984). Gray whales approach the lower Cook Inlet in late March, April, May, and June, and leave again in November and December (Consiglieri *et al.* 1982; Rice and Wolman 1971) but migrate past the mouth of Cook Inlet to and from northern feeding grounds. Some gray whales do not migrate completely from Baja to the Chukchi Sea but instead feed in select coastal areas in the Pacific Northwest, including lower Cook Inlet (Moore *et al.* 2007).

Most of the population follows the outer coast of the Kodiak Archipelago from the Kenai Peninsula in spring or the Alaska Peninsula in fall (Consiglieri *et al.* 1982; Rice and Wolman 1971). Though most gray whales migrate past Cook Inlet, small numbers have been noted by fishers near Kachemak Bay, and north of Anchor Point (BOEM 2015). During the NMFS aerial surveys, gray whales were observed in the month of June in 1994, 2000, 2001, 2005 and 2009 on the east side of Cook Inlet near Port Graham and Elizabeth Island but also on the west side near Kamishak Bay (Shelden *et al.* 2013). One gray whale was sighted as far north at the Beluga River. Additionally, summering gray whales were seen offshore of Cape Starichkof by marine mammal observers monitoring Buccaneer's Cosmopolitan drilling program in 2013 (Owl Ridge 2014). During Apache's 2012 seismic program, nine gray whales were observed in June and July (Lomac-MacNair *et al.* 2013). During Apache's seismic program in 2014, one gray whale was observed (Lomac-MacNair *et al.* 2014). During SAExploration's seismic survey in 2015, no gray whales were observed (Kendall *et al.* 2015). No gray whales were observed during the 2019 Hilcorp seismic survey in lower Cook Inlet (Fairweather Science 2020) or during the 2018 Cook Inlet Pipeline (CIPL) project (Sitkiewicz *et al.* 2018).

Humpback Whale

Humpback whales are found throughout southern Alaska in a variety of marine environments, including open-ocean, near-shore waters, and areas with strong tidal currents (Dahlheim *et al.* 2009). Most humpback whales are migratory and spend winters in the breeding grounds off either Hawaii or Mexico. Humpback whales are regularly present and feeding in Cook Inlet in the summer. Current threats to humpback whales include vessel strikes, spills, climate change, and commercial fishing operations (Muto *et al.* 2021).

Humpback whales worldwide were designated as ''endangered'' under the Endangered Species Conservation Act in 1970, and were listed under the ESA at its inception in 1973. However, on September 8, 2016, NMFS published a final decision that changed the status of humpback whales under the ESA (81 FR 62259), effective October 11, 2016. The decision recognized the existence of 14 distinct population segments (DPSs) based on distinct breeding areas in tropical and temperate waters. Five of the 14 DPSs were classified under the ESA (4 endangered and 1 threatened), while the other 9 DPSs were delisted. Humpback whales found in the project area are predominantly members of the Hawaii DPS, which is not listed under the ESA. However, based on analyses of photo-identification studies in Alaska, members of the Mexico DPS and the Western North Pacific DPS, which are listed as threatened and endangered respectively, are thought to occur in Cook Inlet. Approximately one percent of all humpback whales in Cook Inlet are thought to belong to the endangered Western North Pacific DPS and 11 percent are thought to belong to the threatened Mexico DPS. All other humpback whales present are thought to belong to the non-listed Hawaii DPS (Wade *et al.* 2021). Members of different DPSs are known to intermix on feeding grounds; therefore, all waters off the coast of Alaska should be considered to have ESA-listed humpback whales. Critical habitat was recently designated near the entrance of lower Cook Inlet for Western North Pacific DPS and Mexico DPS humpback whales (86 FR 21082; April 21, 2021); however, Hilcorp's action area does not spatially overlap with any critical habitat designated for humpback whale DPS.

The DPSs of humpback whales that were identified through the ESA listing process do not necessarily equate to the existing MMPA stocks. The stock delineations of humpback whales under the MMPA are currently under review. Until this review is complete, NMFS considers humpback whales in Cook Inlet to be part of the Central North Pacific stock, with a status of endangered under the ESA and designations of strategic and depleted under the MMPA (Muto *et al.* 2021).

In the summer, humpback whales are regularly present and feeding in the Cook Inlet region, including Shelikof Strait, Kodiak Island bays, and the Barren Islands, in addition to Gulf of Alaska regions adjacent to the southeast side of Kodiak Island (especially Albatross Banks), the Kenai and Alaska peninsulas, Elizabeth Island, as well as south of the Aleutian Islands. Humpbacks also may be present in some of these areas throughout autumn (Muto *et al.* 2017).

Humpback whales have been observed during marine mammal surveys conducted in Cook Inlet; however, their presence is largely confined to lower Cook Inlet. During SAExploration's 2015 seismic program, three humpback whales were observed in Cook Inlet; two near the Forelands and one in Kachemak Bay (Kendall *et al.* 2015). During NMFS Cook Inlet beluga whale aerial surveys from 2000 to 2018, there were 88 sightings of 191 estimated individual humpback whales in lower Cook Inlet (Shelden *et al.* 2017). They have been regularly seen near Kachemak Bay during the summer months (Rugh *et al.* 2005). There are observations of humpback whales as far north as Anchor Point, with recent summer observations extending to Cape Starichkof (Owl Ridge 2014). Several

humpback whale sightings occurred lower Cook Inlet between Iniskin Peninsula and Kachemak Bay near Augustine, Barren, and Elizabeth Islands (Shelden *et al.* 2013, 2015, 2017). There were two sightings of three humpback whales observed near Ladd Landing north of the Forelands on the recent Harvest Alaska Cook Inlet Pipeline Extension (CIPL) project (Sitkiewicz *et al.* 2018). There were 14 sightings of 38 humpback whales observed in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). This higher number of humpback whales was expected in the lower Cook Inlet region than Hilcorp's proposed work in the late summer/fall period.

Ferguson *et al.* (2015) identified a biologically important area (BIA), in which humpback whales are known to concentrate for feeding, in the Gulf of Alaska region. The BIA encompasses the waters east of Kodiak Island (the Albatross and Portlock Banks), a target for historical commercial whalers based out of Port Hobron, Alaska (Ferguson *et al.* 2015; Reeves *et al.* 1985; Witteveen *et al.* 2007). This BIA also includes waters along the southeastern side of Shelikof Strait and in the bays along the northwestern shore of Kodiak Island. The highest densities of humpback whales around the Kodiak Island BIA occur from July–August (Ferguson *et al.* 2015). This BIA lies directly south but does not spatially overlap with Hilcorp's proposed action area.

Minke Whale

Minke whales are a non-ESA listed cetacean not commonly found in the Cook Inlet region. Minke whales are not designated as depleted under the MMPA or listed as threatened or endangered under the ESA. Presumably, minke whales breed in warm, low latitude waters during winter, give birth every other year to one calf, and reach sexual maturity at 7 to 9 m (23 to 30 ft) in length (Perrin and Brownell 2009). Potential threats to and vulnerabilities of minke whales include anthropogenic sound emissions underwater, impacts on prey distribution, climate change, fishing operations, vessel strikes, and oil and gas operations (Muto *et al.* 2018).

Minke whales are most abundant in the Gulf of Alaska during summer and occupy localized feeding areas (Zerbini *et al.* 2006). Concentrations of minke whales have occurred along the north coast of Kodiak Island and along the south coast of the Alaska Peninsula (Zerbini *et al.* 2006). The most recent estimate for minke whales specifically between Kenai Fjords and the Aleutian Islands is 1,233 individuals (Zerbini *et al.* 2006). No population estimate for minke whales in the entirety of the north Pacific exists (Muto et al, 2019). During shipboard surveys conducted in 2003, three minke whale sightings were made, all near the eastern extent of the survey from nearshore Prince William Sound to the shelf break (MML, 2003). Minke whales become scarce in the Gulf of Alaska in fall; most whales are thought to leave the region by October (Consiglieri *et al.* 1982). Minke whales are migratory in Alaska, but recently have been observed off Cape Starichkof and Anchor Point year-round (Muto *et al.* 2017).

During Cook Inlet-wide aerial surveys conducted from 1993 to 2004, minke whales were encountered three times (1998, 1999, and 2006), both times off Anchor Point 26 km (16 miles [mi]) northwest of Homer (Shelden *et al.* 2013, 2015, 2017; Shelden and Wade 2019). A minke whale was also reported off Cape Starichkof in 2011 and 2013, suggesting this location is regularly used by minke whales, including during the winter. Several minke whales were recorded off Cape Starichkof in early summer 2013 during exploratory drilling (Owl Ridge 2014), suggesting this location may be used by minke whales year-round. During Apache's 2014 survey, a total of two minke whale groups (totaling three individuals) were observed during this time period, one sighting to the southeast of Kalgin Island and another sighting near Homer (Lomac-MacNair *et al.* 2014). SAExploration noted one minke whale near Tuxedni Bay in 2015 (Kendall *et al.* 2015). There were eight sightings of eight minke whales observed in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). This higher number of minke whales suggests these offshore waters of lower Cook Inlet may be utilized by minke whales in greater numbers than previously estimated, particularly during the fall period. No minke whales were observed during the 2018 CIPL project (Sitkiewicz *et al.* 2018).

Fin Whale

Fin whales are listed as endangered under the ESA in 1990 and depleted under the MMPA. For management purposes, three stocks of fin whales are currently recognized in United States (U.S.) Pacific waters: Alaska (Northeast Pacific), California/Washington/Oregon, and Hawaii. Recent analyses provide evidence that the population structure should be reviewed and possibly updated, however substantially new data on the stock structure is lacking (Muto *et al.* 2019).The Northeast Pacific stock is categorized as a strategic stock. No critical habitat has been designated or proposed for fin whales in the North Pacific.

Fin whales are usually observed as individuals traveling alone, although they are sometimes observed in small groups. Rarely, large groups of 50 to 300 fin whales can travel together during migrations (NMFS 2010a). Fin whales in the Cook Inlet have only been observed as individuals or in small groups. Fin whales are vulnerable to natural and anthropogenic variables. Impacts on prey quality and distribution could affect distribution and energetics. The natural range of fin whales could be expanded due to sea ice melting and expanded available habitat. This could also result in increased exposure to shipping and other commercial activities. Toxicity and resulting deaths, as seen in recent years, from harmful algal blooms producing biotoxins could result from warming waters (Muto *et al.* 2021).

In the U.S. Pacific waters, fin whales are found seasonally in the Gulf of Alaska, Bering Sea, and as far north as the northern Chukchi Sea (Muto *et al.* 2019). Surveys conducted in coastal waters of the Aleutians and the Alaska Peninsula found fin whales occurred primarily from the Kenai Peninsula to the Shumagin Islands and were abundant near the Semidi Islands and Kodiak Island (Zerbini *et al.* 2006). An opportunistic survey conducted on the shelf of the Gulf of Alaska found fin whales concentrated west of Kodiak Island in Shelikof Strait, and in the southern Cook Inlet region. In the northeastern Chukchi Sea, visual sightings and acoustic detections have been increasing, which suggests the stock may be re-occupying habitat used prior to large-scale commercial whaling (Muto *et al.* 2019). Most of these areas are feeding habitat for fin whales. Watkins *et al.* (2000), and Stafford *et al.* (2007) documented high rates of calling along the Alaska coast beginning in August/September and lasting through February. Fin whales are regularly observed in the Gulf of Alaska during the summer months, even though calls are seldom detected during this period (Stafford *et al.* 2007). Instruments moored in the southeast Bering Sea detected calls over the course of a year and found peaks from September to November as well as in February and March (Stafford *et al.* 2010). Delarue *et al.* (2013) detected calls in the northeastern Chukchi Sea from instruments moored from July through October from 2007 through 2010.

Fin whales are rarely observed in Cook Inlet and most sightings occur near the entrance of the inlet. During the

NMFS aerial surveys in Cook Inlet from 2000 to 2018, 10 sightings of 26 estimated individual fin whales in lower Cook Inlet were observed (Shelden *et al.* 2013, 2015, 2017; Shelden and Wade 2019). There were eight sightings of 23 fin whales observed in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). This higher number of fin whale sightings suggests these offshore waters of lower Cook Inlet may be utilized by fin whales in greater numbers than previously estimated, particularly during the fall period.

Beluga Whale

The Cook Inlet beluga whale stock is a small geographically isolated population that is separated from other beluga populations by the Alaska Peninsula. The population is genetically distinct from other Alaska populations suggesting the Peninsula is an effective barrier to genetic exchange (O'Corry-Crowe *et al.* 1997). The Cook Inlet beluga whale population is estimated to have declined from 1,300 animals in the 1970s (Calkins 1989) to about 340 animals in 2014 (Shelden *et al.* 2015). The current population estimate is 279 animals (Shelden and Wade 2019). In 1999, beluga hunters agreed to a moratorium on hunting to protect the species, from 2000 through 2005 one strike per year was allowed and taken in all but 2004, and since 2006 no Cook Inlet belugas have been harvested by subsistence users (Muto *et al.* 2021).

NMFS designated the population as depleted under the MMPA in 2000 and listed it as endangered under the ESA in 2008 when the population failed to recover following a moratorium on subsistence harvest (65 FR 34590; May 31, 2000). In April 2011, NMFS designated critical habitat for the beluga under the ESA (76 FR 20180; April 11, 2011). NMFS finalized the Conservation Plan for the Cook Inlet beluga in 2008 (NMFS 2008a) and the Recovery Plan for Cook Inlet beluga whales in 2016 (NMFS 2016a). During the most recent 10-year time period (2008 to 2018), the population of Cook Inlet belugas experienced a decline of about 2.3 percent per year (Wade *et al.* 2019). Threats that have the potential to impact this stock and its habitat include the following: Changes in prey availability due to natural environmental variability, ocean acidification, and commercial fisheries; climatic changes affecting habitat; predation by killer whales; contaminants; noise; ship strikes; waste management; urban runoff; construction projects; and physical habitat modifications that may occur as Cook Inlet becomes increasingly urbanized (Moore *et al.,* 2000, Lowry *et al.,* 2006, Hobbs *et al.,* 2015, NMFS, 2106). Planned projects that may alter the physical habitat of Cook Inlet include highway improvements; mine construction and operation; oil and gas exploration and development; and expansion and improvements to ports.

Generally, female beluga whales reach sexual maturity at 9 to 12 years old, while males reach maturity later (O'Corry-Crowe 2009); however, this can vary between populations. For example, in Greenland, males in a population of beluga whales were found to reach sexual maturity at 6 to 7 years of age and females at 4 to 7 years. (Heide-Joregensen and Teilmann 1994). Suydam (2009) estimated that 50 percent of females were sexually mature at age 8.25 and the average age at first birth was 8.27 years for belugas sampled near Point Lay. Mating behavior in beluga whales typically occurs between February and June, peaking in March (Burns and Seaman 1986; Suydam 2009). In the Chukchi Sea, the gestation period of beluga whales was determined to be 14.9 months, with a calving interval of two to three years and a pregnancy rate of 0.41, declining after 25 years of age (Suydam 2009). Calves are born between mid-June and mid-July and typically remain with the mother for up to 2 years of age (Suydam 2009).

Several studies (Johnson *et al.* 1989; Klishin *et al.* 2000; Finneran *et al.* 2002; Erbe 2008; white *et al.* 1978; Awbrey *et al.* 1988; Ridgway *et al.* 2001; Finneran *et al.* 2005; Castellote *et al.* 2019) describe beluga whale hearing capabilities. One study on beluga whales captured and released in Bristol Bay, Alaska measured hearing ranges at 4 to 150 kHz with greatest variation between individuals at the high end of the auditory range in combination with frequencies near the maximum sensitivity (Castellote *et al.* 2014). All animals tested heard well up to 128 kHz, with two individuals hearing up to 150 kHz (Castellote *et al.* 2014). Beluga whales are included in the NMFS-identified mid-frequency functional hearing group.

The Cook Inlet beluga stock remains within Cook Inlet throughout the year (Goetz *et al.* 2012a). Two areas, consisting of 7,809 square kilometers (km^2) of marine and estuarine environments considered essential for the species' survival and recovery, were designated critical habitat. However, in recent years the range of the beluga whale has contracted to the upper reaches of Cook Inlet (Rugh *et al.* 2010). Area 1 of the Cook Inlet beluga whale critical habitat encompasses all marine waters of Cook Inlet north of a line connecting Point Possession (61.04° N, 150.37° W) and the mouth of Threemile Creek (61.08.55° N, 151.04.40° W), including waters of the Susitna, Little Susitna, and Chickaloon Rivers below the mean higher high water line (MHHW). This area provides important habitat during ice-free months and is used intensively by Cook Inlet beluga between April and November for feeding and other biological functions (NMFS 2016a).

Since 1993, NMFS has conducted annual aerial surveys in June, July, or August to document the distribution and abundance of beluga whales in Cook Inlet. The collective survey results show that beluga whales have been consistently found near or in river mouths along the northern shores of middle and upper Cook Inlet. In particular, beluga whale groups are seen in the Susitna River Delta, Knik Arm, and along the shores of Chickaloon Bay. Small groups had also been recorded farther south in Kachemak Bay, Redoubt Bay (Big River), and Trading Bay (McArthur River) prior to 1996, but very rarely thereafter. Since the mid-1990s, most beluga whales have been concentrated in shallow areas near river mouths north and east of Beluga River and Point Possession (Hobbs *et al.* 2008). Based on these aerial surveys, there is a consistent pattern of beluga whale presence in the northernmost portion of Cook Inlet from June to October (Rugh *et al.* 2000, 2004a, 2004b, 2005, 2006, 2007).

Though Cook Inlet beluga whales can be found throughout the inlet at any time of year, generally they spend the ice-free months in the upper Cook Inlet, shifting into deeper waters in middle Cook Inlet in winter (Hobbs *et al.* 2008). In 1999, one beluga whale was tagged with a satellite transmitter, and its movements were recorded from June through September of that year. Since 1999, 18 beluga whales in upper Cook Inlet have been captured and fitted with satellite tags to provide information on their movements during late summer, fall, winter, and spring. Using location data from satellite-tagged Cook Inlet belugas, Ezer *et al.* (2013) found most tagged whales were in the lower to middle inlet during January through March, near the Susitna River Delta from April to July) and in the Knik and Turnagain Arms from August to December.

During the spring and summer, beluga whales are generally concentrated near the warmer waters of river mouths where prey availability is high and predator occurrence is low (Moore *et al.* 2000). Beluga whales in Cook Inlet are

believed to mostly calve between mid-May and mid-July, and concurrently breed between late spring and early summer (NMFS 2016a), primarily in upper Cook Inlet. Beluga movement was correlated with the peak discharge of seven major rivers emptying into Cook Inlet. Boat-based surveys from 2005 to the present (McGuire and Stephens 2017), and initial results from passive acoustic monitoring across the entire inlet (Castellote *et al.* 2016) also support seasonal patterns observed with other methods, and other surveys confirm Cook Inlet belugas near the Kenai River during summer months (McGuire and Stephens 2017).

During the summer and fall, beluga whales are concentrated near the Susitna River mouth, Knik Arm, Turnagain Arm, and Chickaloon Bay (Nemeth *et al.* 2007) where they feed on migrating eulachon (Thaleichthys pacificus) and salmon (*Onchorhyncus spp.*) (Moore *et al.* 2000). Data from tagged whales (14 tags between July and March 2000 through 2003) show beluga whales use upper Cook Inlet intensively between summer and late autumn (Hobbs *et al.* 2005). Critical Habitat Area 1 encompasses this summer distribution.

As late as October, beluga whales tagged with satellite transmitters continued to use Knik Arm and Turnagain Arm and Chickaloon Bay, but some ranged into lower Cook Inlet south to Chinitna Bay, Tuxedni Bay, and Trading Bay (McArthur River) in the fall (Hobbs *et al.* 2005). Data from NMFS aerial surveys, opportunistic sighting reports, and satellite-tagged beluga whales confirm they are more widely dispersed throughout Cook Inlet during the winter months (November to April), with animals found between Kalgin Island and Point Possession. In November, beluga whales moved between Knik Arm, Turnagain Arm, and Chickaloon Bay, similar to patterns observed in September (Hobbs *et al.* 2005). By December, beluga whales were distributed throughout the upper to middle Cook Inlet. From January into March, they moved as far south as Kalgin Island and slightly beyond in central offshore waters. Beluga whales also made occasional excursions into Knik Arm and Turnagain Arm in February and March despite ice cover greater than 90 percent (Hobbs *et al.* 2005). Critical Habitat Area 2 encompasses some of the fall and winter feeding grounds in middle Cook Inlet.

Ferguson *et al.* (2015) delineated one 'Small' and 'Resident' BIA for Cook Inlet beluga whales. Small and Resident BIAs are defined as ''areas and time within which small and resident populations occupy a limited geographic extent'' (Ferguson *et al.* 2015). The Cook Inlet beluga whale BIA was delineated using the habitat model results of Goetz *et al.* 2012 and the critical habitat boundaries and overlaps with both Critical Habitat Areas 1 and 2.

During Apache's seismic test program in 2011 along the west coast of Redoubt Bay, lower Cook Inlet, a total of 33 beluga whales were sighted during the survey (Lomac-MacNair *et al.* 2013). During Apache's 2012 seismic program in mid-inlet, a total of 151 sightings consisting of an estimated 1,463 beluga whales were observed (Lomac-MacNair *et al.* 2014). During SAExploration's 2015 seismic program, a total of eight sightings of 33 estimated individual beluga whales were visually observed during this time period and there were two acoustic detections of beluga whales (Kendall *et al.* 2015). During Harvest Alaska's recent CIPL project on the west side of Cook Inlet in between Ladd Landing and Tyonek Platform, a total of 143 beluga whale sightings (814 individuals) were observed almost daily from May 31 to July 11, even though observations spanned from May 9 through September 15 (Sitkiewicz *et al.* 2018). There were two beluga whale carcasses observed by the project vessels in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall which were reported to the NMFS Marine Mammal Stranding Network (Fairweather Science 2020). Both carcasses were moderately decomposed when they were sighted by the PSOs. Daily aerial surveys specifically for beluga whales were flown over the lower Cook Inlet region, but no beluga whales were observed.

Killer Whale

Based on data regarding association patterns, acoustics, movements, and genetic differences, eight killer whale stocks are now recognized within the Pacific U.S. Exclusive Economic Zone. Two different stocks of killer whales inhabit the Cook Inlet region of Alaska: The Alaska Resident Stock and the Gulf of Alaska, Aleutian Islands, Bering Sea Transient Stock (Muto *et al.* 2021). The Alaska Resident Stock and the Gulf of Alaska, Aleutian Islands, Bering Sea Transient Stock of killer whales are not designated as depleted under the MMPA or listed as threatened or endangered under the ESA. Reliable data on population trends for these killer whale stocks are unavailable (Muto *et al.* 2021).

Resident and transient killer whales from the Alaska Resident Stock and the Gulf of Alaska, Aleutian Islands, and Bering Sea Transient Stock occur in Cook Inlet (Allen and Angliss 2015), though rarely in middle and upper Cook Inlet. Transient killer whales feed on beluga whales and other marine mammals, and resident populations feed on anadromous fish (Shelden *et al.* 2003). The likelihood of killer whale occurrence depends on prey availability (NOAA 2019). Threats to and vulnerabilities of killer whales include natural causes, such as predation, and anthropogenic factors such as climate change, fishing operations and vessel strikes (Muto *et al.* 2016).

Killer whales are occasionally observed in lower Cook Inlet, especially near Homer and Port Graham (Shelden *et al.* 2003; Rugh *et al.* 2005). The few whales that have been photographically identified in lower Cook Inlet belong to resident groups more commonly found in nearby Kenai Fjords and Prince William Sound (Shelden *et al.* 2003). The availability of prey species largely determines the likeliest times for killer whales to be in the area. During aerial surveys conducted between 1993 and 2004, killer whales were observed on only three flights, all in the Kachemak and English Bay area (Rugh *et al.* 2005). However, anecdotal reports of killer whales feeding on belugas in middle and upper Cook Inlet began increasing in the 1990s, possibly in response to declines in sea lion and harbor seal prey elsewhere (Shelden *et al.* 2003).

One killer whale group of two individuals was observed during the 2015 SAExploration seismic program near the North Foreland (Kendall *et al.* 2015). During NMFS aerial surveys, killer whales were observed in 1994 (Kamishak Bay), 1997 (Kachemak Bay), 2001 (Port Graham), 2005 (Iniskin Bay), 2010 (Elizabeth and Augustine Islands), and 2012 (Kachemak Bay; Shelden *et al.* 2013). Eleven killer whale strandings have been reported in Turnagain Arm, six in May 1991, and five in August 1993. There were six sightings of 21 killer whales observed in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). This species is expected to be rarely seen in upper Cook Inlet but may be encountered in the middle and lower Inlet. However, no killer whales were observed during the 4-month CIPL project in middle Cook Inlet in 2018 (Sitkiewicz *et al.* 2018).

Harbor Porpoise

In Alaskan waters, three stocks of harbor porpoises are currently recognized for management purposes: Southeast Alaska, Gulf of Alaska, and Bering Sea Stocks (Muto *et al.* 2019). Porpoises found in Cook Inlet belong to the Gulf of Alaska Stock which is distributed from Cape Suckling to

Unimak Pass and most recently was estimated to number 31,046 individuals (Muto *et al.* 2019). Harbor porpoises are regularly seen throughout Cook Inlet (Nemeth *et al.* 2007), especially during spring eulachon and summer salmon runs. Harbor porpoises are not designated as depleted under the MMPA or listed as threatened or endangered under the ESA.

Harbor porpoises primarily frequent the coastal waters of the Gulf of Alaska and Southeast Alaska (Dahlheim *et al.* 2000, 2008), typically occurring in waters less than 100 m deep (Hobbs and Waite 2010). The range of the Gulf of Alaska stock includes the entire Cook Inlet, Shelikof Strait, and the Gulf of Alaska. Harbor porpoises have been reported in lower Cook Inlet from Cape Douglas to the West Foreland, Kachemak Bay, and offshore (Rugh *et al.* 2005). Although they have been frequently observed during aerial surveys in Cook Inlet (Shelden *et al.* 2014), most sightings are of single animals, and are concentrated at Chinitna and Tuxedni bays on the west side of lower Cook Inlet (Rugh *et al.* 2005) and in the upper inlet. The occurrence of larger numbers of porpoise in the lower Cook Inlet may be driven by greater availability of preferred prey and possibly less competition with beluga whales, as belugas move into upper inlet waters to forage on Pacific salmon (*Oncorhynchus spp.*) during the summer months (Shelden *et al.* 2014). Recent passive acoustic research in Cook Inlet by Alaska Department of Fish and Game (ADF&G) and MML have indicated that harbor porpoises occur more frequently than expected, particularly in the West Foreland area in the spring (Castellote *et al.* 2016).

The harbor porpoise frequently has been observed during summer aerial surveys of Cook Inlet, with most sightings of individuals concentrated at Chinitna and Tuxedni Bays on the west side of lower Cook Inlet (Rugh *et al.* 2005). Mating likely occurs from June or July to October, with peak calving in May and June (Consiglieri *et al.* 1982). Small numbers of harbor porpoises have been consistently reported in the upper Cook Inlet between April and October, except for a recent survey that recorded higher numbers than typical. NMFS aerial surveys have routinely identified many harbor porpoise sightings throughout Cook Inle. During Apache's 2012 seismic program, 137 sightings (190 individuals) were observed between May and August (Lomac-MacNair *et al.* 2013). Lomac-MacNair *et al.* 2014 identified 77 groups of harbor porpoise totaling 13 individuals during Apache's 2014 seismic survey, both from vessels and aircraft, during the month of May. During SAExploration's 2015 seismic survey, 52 sightings (65 individuals) were observed north of the Forelands (Kendall *et al.* 2015). There were 2 sightings of 3 harbor porpoises observed during the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). A total of 29 sightings (44 individuals) were observed north of the Forelands from May to September during the Harvest Alaska CIPL project (Sitkiewicz *et al.* 2018). During jack-up rig moves in 2021, a Protected Species Observer (PSO) observed two individual harbor porpoises in middle Cook Inlet, one in July and one in October.

Dall's Porpoise

Dall's porpoises are widely distributed across the North Pacific, but they are infrequently sighted in upper Cook Inlet (Muto *et al.* 2020). Dall's porpoises have been observed in lower Cook Inlet, around Kachemak Bay, and rarely near Anchor Point (BOEM 2015). Dall's porpoises are not designated as depleted under the MMPA or listed as threatened or endangered under the ESA (Muto *et al.* 2019). Threats to and vulnerabilities of Dall's porpoises include natural and anthropogenic factors such as habitat modifications and climate change. The nearshore areas, bays, channels, and inlets where Dall's porpoises frequent are of particular concern. These areas are subject to substantial changes with urbanization and industrialization, including waste management and nonpoint source runoff (Linnenschmidt *et al.* 2013).

Throughout most of the eastern North Pacific they are present during all months of the year, although there may be seasonal onshore-offshore movements along the west coast of the continental U.S. and winter movements of populations out of areas with ice such as Prince William Sound (Muto *et al.* 2019). No Dall's porpoises were observed during the CIPL project monitoring program in middle Cook Inlet in 2018 (Sitkiewicz *et al.* 2018). Dall's porpoises were observed (two groups of three individuals) during Apache's 2014 seismic survey which occurred in the summer months (Lomac-MacNair *et al.* 2014). Dall's porpoises were observed during the month of June in 1997 (Iniskin Bay), 199 (Barren Island), and 2000 (Elizabeth Island, Kamishak Bay and Barren Island) (Shelden *et al.* 2013). Dall's porpoises have been observed in lower Cook Inlet, including Kachemak Bay and near Anchor Point (Owl Ridge 2014). One Dall's porpoise was observed in August north of Nikiski in the middle of the Inlet during SAExploration's 2015 seismic program (Kendall *et al.* 2015). There were 10 sightings of 30 Dall's porpoises observed during the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020).

Steller Sea Lion

The Western DPS of Steller sea lions is currently listed as endangered under the ESA (55 FR 49204; November 26, 1990) and designated as depleted under the MMPA. Critical habitat was designated on August 27, 1993 (58 FR 45269; August 27, 1993) south of the proposed action area in the Cook Inlet region. The critical habitat designation for the Western DPS of Steller sea lions includes a 37 km buffer around all major haul outs and rookeries, and associated terrestrial, atmospheric, and aquatic zones, plus three large offshore foraging areas, as well as designated no entry zones around rookeries (50 CFR 223.202). Designated critical habitat is located outside Cook Inlet at Gore Point, Elizabeth Island, Perl Island, and Chugach Island (NMFS 2008b). The Western DPS of the Steller sea lion is defined as all populations west of longitude 144° W to the western end of the Aleutian Islands.

Steller sea lions are not migratory animals but exhibit wide dispersion in the non-breeding season (Loughlin 1997). They are polygynous in nature, with one male typically breeding with large numbers of females. Steller sea lions tend to haul out in large groups.

Underwater vocalizations of Steller sea lions have been noted to include belches, barks, and clicks (Kastelein *et al.* 2005). Audiograms have revealed a maximum underwater hearing sensitivity at 77 dB RL at 1kHz for a male Steller sea lion, with a range of best hearing at 10 dB from the maximum sensitivity, of between 1 and 16 kHz. His average pre-stimulus responses occurred at low frequency signals. Similar audiograms of a female Steller sea lion revealed a maximum hearing sensitivity of 73 dB received level, occurring at 25 kHz, indicating that low frequency sounds are audible to Steller sea lions (Kastelein *et al.* 2005).

Steller sea lions feed largely on walleye pollock (*Theragra chalcogramma*), salmon (*Onchorhyncus spp.*), and arrowtooth flounder (*Atheresthes stomias*) during the summer, and walleye pollock and Pacific cod (*Gadus macrocephalus*) during the winter (Sinclair and Zeppelin 2002). Except for salmon, these species are not found in

abundance in upper Cook Inlet (Nemeth *et al.* 2007). Threats to and vulnerabilities of Steller sea lions include natural and anthropogenic factors, including depletion of prey availability from fishing activities, climate change, disease, contaminants, predation by killer whales, incidental take, and illegal and legal shooting (Atkinson *et al.* 2008, NMFS 2008), harmful algal blooms (Lefebvre *et al.* 2016), disease proliferation from warming waters (VanWormer *et al.* 2019), and potentially metal and contaminant exposure (Rea *et al.* 2013; Beckmen *et al.* 2016, Keogh *et al.* 2020).

Steller sea lions inhabit lower Cook Inlet, especially near Shaw Island and Elizabeth Island (Nagahut Rocks) haul out sites (Rugh *et al.* 2005) but are rarely seen in upper Cook Inlet (Nemeth *et al.* 2007). Steller sea lions occur in Cook Inlet but south of Anchor Point around the offshore islands and along the west coast of the upper inlet in the bays (Chinitna Bay, Iniskin Bay, etc.) (Rugh *et al.* 2005). Portions of the southern reaches of the lower inlet are designated as critical habitat, including a 37 km (20 nautical mile) buffer around all major haul out sites and rookeries. Rookeries and haul out sites in lower Cook Inlet include those near the mouth of the inlet, which are far south of the Action Area.

Steller sea lions have been observed during marine mammal surveys conducted in Cook Inlet. In 2012, during Apache's 3D Seismic surveys, there were three sightings of approximately four individuals in upper Cook Inlet (Lomac-MacNair *et al.* 2013). Marine mammal observers associated with Buccaneer's drilling project off Cape Starichkof observed seven Steller sea lions during the summer of 2013 (Owl Ridge 2014). During SAExploration's 3D Seismic Program in 2015, four Steller sea lions were observed in Cook Inlet. One sighting occurred between the West and East Forelands, one near Nikiski and one northeast of the North Foreland in the center of Cook Inlet (Kendall *et al.* 2015). There were five sightings of five Steller sea lions observed during the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). One sighting of two individuals occurred during the CIPL project in 2018 in middle Cook Inlet (Sitkiewicz *et al.* 2018). During NMFS Cook Inlet beluga whale aerial surveys from 2000 to 2016, there were 39 sightings of 769 estimated individual Steller sea lions in lower Cook Inlet (Shelden *et al.* 2017). Sightings of large congregations of Steller sea lions during NMFS aerial surveys occurred outside the Action Area, on land in the mouth of Cook Inlet (*e.g.,* Elizabeth and Shaw Islands).

California Sea Lion

California sea lions in the U.S. are not listed as endangered or threatened under the ESA or as depleted or strategic under the MMPA. The growth rate of the species is approximately seven percent annually (Carretta *et al.* 2020). There is limited information on the presence of California sea lions in Alaska. California sea lion presence in Alaska was correlated with increasing population numbers within their southern breeding range (Maniscalco *et al.* 2004). California sea lions are not commonly observed in Alaska. When they are observed, they are often alone or, less commonly, in groups of two or more. They are most often associated with Steller sea lions at their haulouts and rookeries (Maniscalco *et al.* 2004). Threats to and vulnerabilities of California sea lions include natural and anthropogenic factors including climate change, exposure to harmful algal neurotoxins (Scholin *et al.* 2000, Brodie *et al.* 2006, Ramsdell and Zabka 2008), shootings, entrainment in industrial facilities, fishing gear interactions, vessel strikes, and human disturbance (Muto *et al.* 2019).

California sea lions are not typically observed farther north than southeast Alaska, and sightings are very rare in Cook Inlet. California sea lions have not been observed during the annual NMFS aerial surveys in Cook Inlet. However, a sighting of two California sea lions was documented during the Apache 2012 seismic survey (Lomac-MacNair *et al.* 2013). Additionally, NMFS' anecdotal sighting database has four sightings in Seward and Kachemak Bay. There were no California sea lions observed during the 2019 Hilcorp lower Cook Inlet seismic survey (Fairweather Science 2020) or the CIPL project in 2018 (Sitkiewicz *et al.* 2018).

Harbor Seal

In 2010, NMFS and their co-management partners, the Alaska Native Harbor Seal Commission, defined 12 separate stocks of harbor seals based largely on genetics. The harbor seal stocks present in the action area are from the Cook Inlet/Shelikof stock. No harbor seal stocks in Alaska are designated as depleted under the MMPA or listed as threatened or endangered under the ESA (Muto *et al.* 2019).

In Cook Inlet, large harbor seal haulout areas are located in lower Cook Inlet, with occurrence in upper inlet coinciding with prey availability. Harbor seals frequent the Susitna River and other rivers feeding into upper Cook Inlet when eulachon and salmon are migrating in those areas (NMFS, 2003). Harbor seals haul out on rocks, reefs, beaches, and drifting glacial ice. Prey species include capelin, eulachon, cod, pollock, flatfish, shrimp, octopus, and squid. Threats to and vulnerabilities of harbor seals include natural and anthropogenic factors including climate change, shipping, and tour vessel traffic (Muto *et al.* 2021).

The major haul out sites for harbor seals are located in lower Cook Inlet and their presence in middle and upper Cook Inlet is seasonal. In Cook Inlet, seal use of western habitats is greater than use of the eastern coastline (Boveng *et al.* 2012). NMFS has documented a strong seasonal pattern of more coastal and restricted spatial use during the spring and summer for breeding, pupping, and molting, and more wide-ranging seal movements within and outside of Cook Inlet during the winter months (Boveng *et al.* 2012). Large-scale movement patterns indicate a portion of harbor seals captured in Cook Inlet move out of the area in the fall, and into habitats within Shelikof Strait, Northern Kodiak Island, and coastal habitats of the Alaska Peninsula, and are most concentrated in Kachemak Bay, across Cook Inlet toward Iniskin and Iliamna Bays, and south through the Kamishak Bay, Cape Douglas, and Shelikof Strait regions (Boveng *et al.* 2012).

The Cook Inlet/Shelikof Stock is distributed from Anchorage into lower Cook Inlet during summer and from lower Cook Inlet through Shelikof Strait to Unimak Pass during winter (Boveng *et al.* 2012). Large numbers concentrate at the river mouths and embayments of lower Cook Inlet, including the Fox River mouth in Kachemak Bay, and several haul outs have been identified on the southern end of Kalgin Island in lower Cook Inlet (Rugh *et al.* 2005; Boveng *et al.* 2012). Montgomery *et al.* (2007) recorded over 200 haul-out sites in lower Cook Inlet alone.

NMFS aerial surveys have routinely identified many harbor seal sightings throughout Cook Inlet over the past 20 years of survey effort. During Apache's 2012 seismic program, harbor seals were observed in the project area from early May until the end of the seismic operations in late September (Lomac-MacNair *et al.* 2013). Up to 100 harbor seals were observed hauled out at the mouths of the Theodore and Lewis rivers during monitoring activity. During Apache's 2014 seismic program, 492 groups of harbor seals (613 individuals) were observed; this highest sighting rate of any marine mammal

observed during the summer of 2014 (Lomac-MacNair *et al.* 2014). During SAExploration's 2015 seismic survey, 823 sightings (1,680 individuals) were observed north and between the Forelands (Kendall *et al.* 2015). Recently, a total of 313 sightings (316 individuals) were observed near Ladd Landing for the Harvest Alaska CIPL project during the summer (Sitkiewicz *et al.* 2018). There were 10 sightings of 10 harbor seals observed during the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science 2020). During a Hilcorp jack-up rig move in 2021, one pinniped of an unidentified species was observed in July in middle Cook Inlet.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 5.

TABLE 5—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

The proposed project includes the use of three tugs towing a jack-up rig, which would emit consistent, low levels of noise into a small portion of Cook Inlet for an extended period of time. Hilcorp's tugging and positioning activities would occur for approximately 16 days in Year 1 and 16 days in Year 2 to support overall production and well plug and abandonment operations that would occur across 210 days in Year 1 and 180 days in Year 2. Unlike projects that involve discrete noise sources with known potential to harass marine mammals (*e.g.,* pile driving, seismic surveys), both the noise sources and impacts from the tugs towing the jack-up rig are less well documented. In light of the aforementioned court decision we have re-examined the available information. The various scenarios that may occur during this project extend from tugs in a stationary mode, positioning the drill rig to pulling the jack-up rig at nearly full power against strong tides. Our assessments of the potential for harassment of marine mammals incidental to Hilcorp's tug activities specified here are conservative in light of the general Level B harassment exposure thresholds, the fact that NMFS is still in the process of developing analyses of the impact that non-quantitative contextual factors have on the likelihood of Level B harassment occurring, and the nature and duration of the particular tug activities analyzed here.

The proposed project has the potential to harass marine mammals from exposure to noise and the physical presence of working vessels (*e.g.,* three tug configuration) as well as associated noise with the positioning of the jack-up rig. In this case, NMFS considers potential for harassment from the collective use of these technologies working in a concentrated area (relative to the entire Cook Inlet) for an extended period of time (when making multiple positioning attempts) and noise created when moving the jack-up rig using three tugs. Essentially, the project area will become a concentrated work area in an otherwise non-industrial setting for a period of several days. Accordingly the Estimated Take section proposes to authorize take, by Level B harassment,

from tug towing activities over the course of 16 days of activity each year.

Auditory Effects

NMFS defines a noise-induced threshold shift (TS) as ''a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level'' (NMFS, 2018). The amount of threshold shift is customarily expressed in dB (ANSI 1995, Yost 2007). A TS can be permanent (PTS) or temporary (TTS). As described in NMFS (2016), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral). When analyzing the auditory effects of noise exposure, it is often helpful to broadly categorize sound as either impulsive—noise with high peak sound pressure, short duration, fast rise-time, and broad frequency content—or non-impulsive. For example, when considering auditory effects, vibratory pile driving is considered a non-impulsive source while impact pile driving is treated as an impulsive source. The sounds produced by tugs towing and positioning the jack-up rig are characterized as non-impulsive sounds.

Permanent Threshold Shift—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (see NMFS 2018 for review).

Temporary Threshold Shift—NMFS defines TTS as a temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Based on data from cetacean TTS measurements (see Finneran 2015 for a review), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2002; Finneran, 2015).

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during times when hearing is critical, such as for successful mother/calf interactions, could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Masking

Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions, but only if the noise spectrum overlaps with the hearing sensitivity of the marine mammal (Southall *et al.,* 2007; Clark *et al.,* 2009; Hatch *et al.,* 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.,* 2009). Acoustic masking is when other noises such as from human sources interfere with animal detection and/or interpretation of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs in the frequency band that the animals utilize. Since noises generated from tugs towing and positioning are mostly concentrated at low frequency ranges, with a small concentration in high frequencies as well, these activities likely have less effect on mid-frequency echolocation sounds by odontocetes (toothed whales) such as Cook Inlet beluga whales. However, lower frequency noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. Low-frequency noise may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (*e.g.,* Clark *et al.,* 2009) and cause increased stress levels (*e.g.,* Holt *et al.,* 2009). Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at population, community, or even ecosystem levels, in addition to individual levels. Masking affects both senders and receivers of the signals and at higher levels for longer durations could have long-term chronic effects on marine mammal species and populations. However, the noise generated by the tugs will not be concentrated in one location or for more than five hours per day and in the same geographic location for only two days per well site.

Behavioral Disturbance

Finally, exposure of marine mammals to certain sounds could result in behavioral disturbance (Richardson *et al.,* 1995), not all of which constitutes harassment under the MMPA. The onset of behavioral disturbance from anthropogenic noise depends on both external factors (*e.g.,* characteristics of noise sources and their paths) and the receiving animals (*e.g.,* hearing, behavioral state, experience, demography) and is difficult to predict (Southall *et al.,* 2007, 2021). Currently NMFS uses a received level of 160 dB re 1 micro Pascal (μPa) root mean square (rms) to predict the onset of behavioral harassment from impulse noises (such as impact pile driving), and 120 dB re 1 μPa (rms) for continuous noises (such as operating dynamic positioning (DP) thrusters), although in certain circumstances there may be contextual factors that alter our assessment of the onset of behavioral harassment. No impulsive noise within the hearing range of marine mammals is expected from Hilcorp's proposed activities. For the tug towing and positioning activities, only the 120 dB re 1 μPa (rms) threshold is considered because only continuous noise sources would be generated.

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, moving

direction and/or speed, reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding), visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping), avoidance of areas where sound sources are located, and/or flight responses. Pinnipeds may increase their haul-out time, possibly to avoid in-water disturbance (Thorson and Reyff 2006). These potential behavioral responses to sound are highly variable and context-specific and reactions, if any, depend on species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day, and many other factors regarding the source eliciting the response (Richardson *et al.,* 1995; Wartzok *et al.,* 2004; Southall *et al.,* 2007). For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC 2003; Wartzok *et al.,* 2004). The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be biologically significant if the change affects growth, survival, and/or reproduction, which depends on the severity, duration, and context of the effects.

In consideration of the range of potential effects (PTS to behavioral disturbance), we consider the potential exposure scenarios and context in which species would be exposed to tug-related activity. Cook Inlet beluga whales may be present in low numbers during the work; therefore, some individuals may be reasonably expected to be exposed to elevated sound levels, including briefly those that exceed the Level B harassment threshold for continuous noise. However, beluga whales are expected to be transiting through the area, given this work is proposed primarily in middle Cook Inlet (as described in the Description of Marine Mammals in the Area of Specified Activities section), thereby limiting exposure duration, as belugas in the area are expected to be headed to or from the concentrated foraging areas farther north near the Beluga River, Susitna Delta, and Knik and Turnigan Arms. Similarly, humpback whales, fin whales, minke whales, killer whales, California sea lion, and Steller sea lions are not expected to remain in the area of the tugs. Dall's porpoise, harbor porpoise, and harbor seal have been sighted with more regularity than many other species during oil and gas activities in Cook Inlet but due to the transitory nature of porpoises, they are unlikely to remain at any particular well site for the full duration of the noise-producing activity. Because of this and the relatively low-level sources, the likelihood of PTS and TTS over the course of the tug activities is discountable. Harbor seals may linger or haul-out in the area but they are not known to do so in any large number or for extended periods of time (there are no known major haul-outs or rookeries coinciding with the well sites). Here we find there is small potential for TTS over the course of tug activities but again, PTS is not likely due to the types of sources involved in the project.

Given most marine mammals are likely transiting through the area, exposure is expected to be brief but, in combination with the actual presence of the tug and jack-up rig configuration, may result in animals shifting pathways around the work site (*e.g.,* avoidance), increasing speed or dive times, or cessation of vocalizations. The likelihood of no more than a short-term, localized disturbance response is supported by data indicating belugas regularly pass by industrialized areas such as the Port of Anchorage; therefore, we do not expect abandonment of their transiting route or other disruptions of their behavioral patterns. We also anticipate some animals may respond with such mild reactions to the project that the response would not be detectable. For example, during low levels of power output (*e.g.,* while tugs may be operating at low power because of favorable conditions), the animals may be able to hear the work but any resulting reactions, if any, are not expected to rise to the level of take.

While in some cases marine mammals have exhibited little to no obviously detectable response to certain common or routine industrialized activity (Cornick et al, 2011), it is possible some animals may at times be exposed to received levels of sound above the Level B harassment threshold. This potential exposure in combination with the nature of the tug and jack-up rig configuration (*e.g.* difficult to maneuver, potential need to operate at night) means it is possible that take could occur over the total estimated period of tug activities; therefore, NMFS in response to Hilcorp's IHA application proposes to authorize take by Level B harassment from Hilcorp's use of tugs towing a jack-up rig for both positioning and straight-line tug activities.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determinations.

Harassment is the only type of take reasonably expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to the tugs towing and positioning the jack-up rig. Based on the nature of the activity, Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level

B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance or harassment from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Accordingly, based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to reasonably estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 µPa)) for continuous (*e.g.,* vibratory pile-driving, drilling) and above RMS SPL, 160 dB re 1 µPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

Hilcorp's activity includes the use of continuous (tug towing and positioning the rig) sources, and therefore the RMS SPL 120 dB re 1 µPa is applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Hilcorp's proposed activity includes the use of non-impulsive (tugs towing rig) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-Impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

As described above in the Detailed Description of the Specific Activity, based on in situ measurements of Hilcorp's tug and a review of the available literature of tugs under load, a source level of 185 dB re 1 µPa was used for Hilcorp's three tug configuration for towing the jack-up-rig. Hilcorp contracted SLR Consulting to model the extent of the Level B harassment isopleth as well as the extent of the PTS isopleth for their proposed activity.

Rather than applying practical spreading loss, SLR created a more detailed propagation loss model in an effort to improve the accuracy of the results by considering the influence of environmental variables (*e.g.* bathymetry) at the specific well sites, as Hilcorp's operational locations are known in advance. Modeling was conducted using dBSea software. The fluid parabolic equation modeling algorithm was used with 5 Padé terms (see pg. 57 in Hilcorp's application for more detail) to calculate the transmission loss between the source and the receiver at low frequencies (1/3-octave bands, 31.5 Hz up to 1 kHz). For higher frequencies (1 kHz up to 8 kHz) the ray tracing model was used with 1,000 reflections for each ray. Sound sources were assumed to be omnidirectional and modeled as points. The received sound levels for the project were calculated as follows: (1) One-third octave source spectral levels were obtained via reference spectral curves with subsequent corrections based on their corresponding overall source levels; (2) Transmission loss was modeled at one-third octave band central frequencies along 100 radial paths at regular increments around each source location, out to the maximum range of the bathymetry data set or until constrained by land; (3) The bathymetry variation of the vertical plane along each modeling path was obtained via interpolation of the bathymetry dataset which has 83 m grid resolution; (4) The one-third octave source levels and transmission loss were combined to obtain the received levels as a function of range, depth, and frequency; and (5) The overall received levels were calculated at a 1-m depth resolution along each propagation path by

summing all frequency band spectral levels.

Model Inputs—Bathymetry data used in the model was collected from the NOAA National Centers for Environmental Information (AFSC 2019). Using NOAA's temperature and salinity data, sound speed profiles were computed for depths from 0 to 100 meters for May, July, and October to capture the range of possible sound speed depending on the time of year Hilcorp's work could be conducted. These sound speed profiles were compiled using the Mackenzie Equation (1981) and are presented in Table 8 of Hilcorp's application. Geoacoustic parameters were also incorporated into the model. The parameters were based on substrate type and their relation to depth. These parameters are presented in Table 9 of Hilcorp's application.

Detailed broadband sound transmission loss modeling in dBSea used the source level of 185 dB re 1 µPa at 1 m calculated in one-third octave band levels (31.5 Hz to 64,000 Hz) for frequency dependent solutions. The frequencies associated with tug sound sources occur within the hearing range of marine mammals in Cook Inlet. Received levels for each hearing marine mammal group based on one-third octave auditory weighting functions were also calculated and integrated into the modeling scenarios of dBSea. For modeling the distances to relevant PTS thresholds, a weighting factor adjustment was not used; instead, the data on the spectrum associated with their source was used and incorporated the full auditory weighting function for each marine mammal hearing group.

Because Hilcorp plans to use the tugs towing the jack-up-rig for essentially two functions (positioning and towing), the activity was divided into two parts (stationary and mobile) and two approaches were taken for modeling the relevant isopleths.

Stationary—For stationary activity, two locations representative of where tugs will be stationary positioning the jack-up rig were selected for the model. These locations are in middle Cook Inlet near the Tyonek platform, and in lower Trading Bay where the production platforms are located, with water depths of 40 m and 20 m respectively. The modeling at these locations assumed a stationary five-hour exposure to a broadband spectrum of 185 dB as described above. A five-hour exposure duration was chosen to account for the up to five-hour positioning attempts on individual days as well as events where the tugs need to hold the jack-up rig while waiting for a following tide. Stationary model results are presented in Table 7.

Mobile—For the mobile portion of the activity, a representative route was used from the Rig Tender's dock in Nikiski to the Tyonek platform, the northernmost platform in Cook Inlet (representing Middle Cook Inlet), as well as from the Tyonek Platform to the Dolly Varden platform in lower Trading Bay and then from the Dolly Varden platform back to the Rig Tender's Dock in Nikiski. This route is representative of a typical route the tugs may take; the specific route is not yet known because the order in which platforms will be drilled with the jack-up rig is not yet known. The lowest threshold for the onset of PTS is for high frequency cetaceans at 173 dB. Based on a source level of 185 dB, and assuming practical spreading, the high frequency cetacean PTS threshold of 173 dB would be reached at 6.3 meters away from the source. The mobile source modeling assumed a transit speed of 2.06 m/s for the tug configuration. With an assumed vessel speed of 2.06 m/s, it would take the vessel 6.11 seconds to traverse a distance of two times the radius, with two times the radius used because the source is omnidirectional and the ship is moving in a straight line. Although a source level of 185 dB incorporates the use of three tugs simultaneously, because the three tugs will likely not be perfectly aligned in space (*e.g.* one could lag slightly behind the forward two), three separate six second exposures were summed (one for each tug passing in space) to arrive at a total duration of exposure of 18 seconds. While it is possible the duration of exposure could be as short as six seconds if all tugs were perfectly aligned, separate exposures for each tug were considered as the exact formation of the tugging vessels at any given time is unknown. Mobile source model results are presented in Table 8.

Because there is no temporal component associated with NMFS' current Level B threshold, making it a potentially conservative assumption given the transitory nature of the rig towing activity, the results of the modeled distance to the 120 dB threshold for both stationary and mobile tug use are presented in Table 9 below. The average of these distances was used for calculation of estimated exposure to Level B harassment (3,850 m).

The locations used in the stationary and mobile source models are depicted in Figure 2 below.

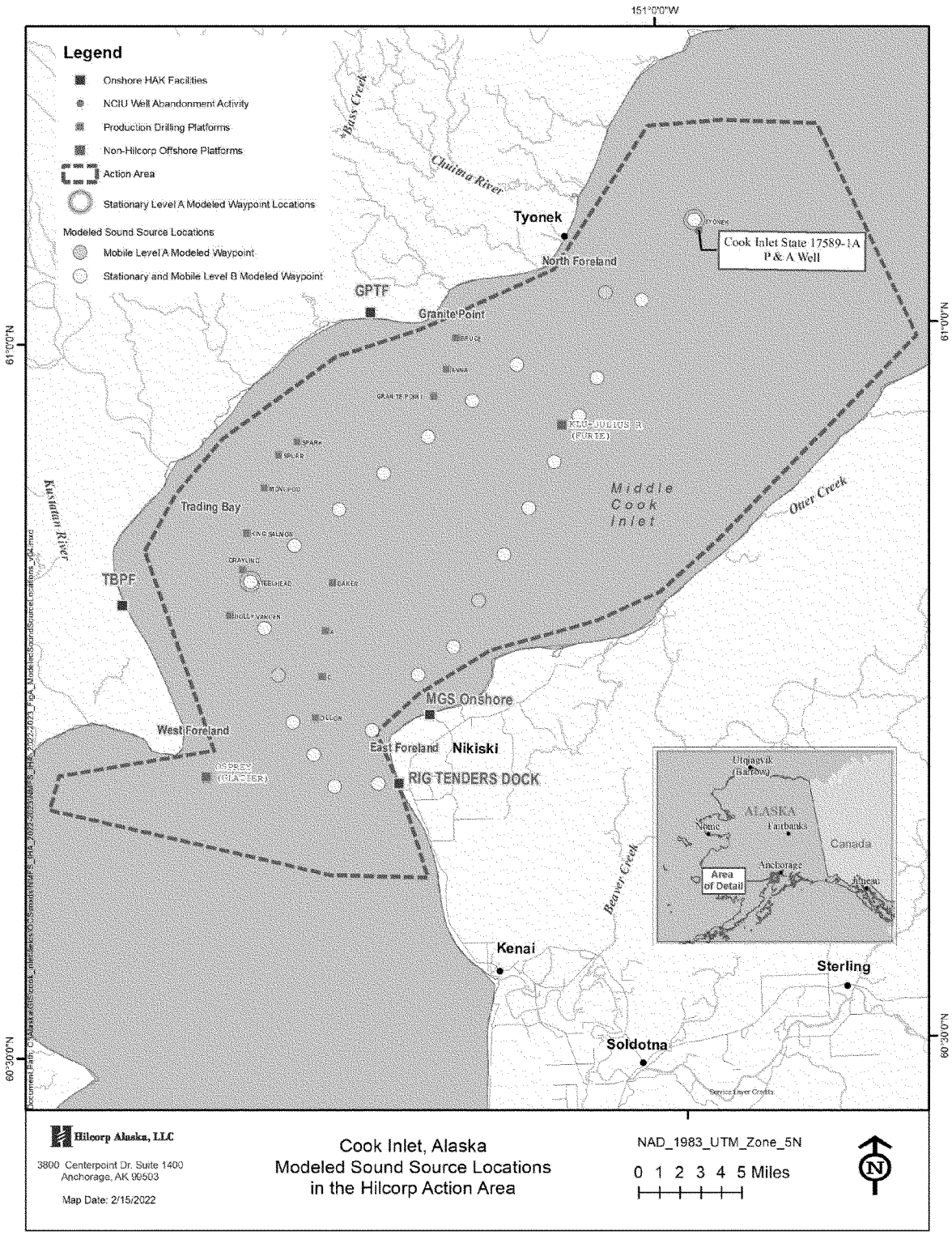

Figure 2. Locations Used for Stationary and Mobile Isopleth Models

The outputs of the mobile and stationary models as distances to the relevant threshold (in meters) are presented below in Tables 7–9.

TABLE 7—AVERAGE DISTANCES TO PTS THRESHOLDS FOR STATIONARY ACTIVITY

Location	Season	Average distances (m) to PTS threshold by functional hearing group				
		LF	MF	HF	PW	OW
Trading Bay	May	100	72	716	59	
Trading Bay	July	122	73	697	63	
Trading Bay	October	98	72	694	59	
Middle Cook Inlet	May	83	83	643	77	
Middle Cook Inlet	July	89	85	664	78	
Middle Cook Inlet	October	80	84	661	78	
Average		95	78	679	69	0

TABLE 8—AVERAGE DISTANCES TO PTS THRESHOLDS FOR MOBILE ACTIVITY

Location	Season	Average distances (m) to PTS threshold by functional hearing group				
		LF	MF	HF	PW	OW
M2	May			10		
M2	July			5		
M2	October			10		
M11	May			10		
M11	July			5		
M11	October			10		
M22	May			10		
M22	July			5		
M22	October			10		
Average		0	0	8	0	0

TABLE 9—AVERAGE DISTANCES TO LEVEL B THRESHOLD (STATIONARY AND MOBILE)

[120 dB]

Waypoint	Average distance to 120 dB threshold (m)			Season average distance to threshold (m)
	May	July	October	
M1	4,215	3,911	4,352	4,159
M2	3,946	3,841	4,350	4,046
M3	4,156	3,971	4,458	4,195
M4	4,040	3,844	4,364	4,083
M5	4,053	3,676	4,304	4,011
M6	3,716	3,445	3,554	3,572
M7	2,947	2,753	2,898	2,866
M8	3,270	3,008	3,247	3,175
M9	3,567	3,359	3,727	3,551
M10	3,600	3,487	3,691	3,593
M11	3,746	3,579	4,214	3,846
M12	3,815	3,600	3,995	3,803
M13	4,010	3,831	4,338	4,060
M14	3,837	3,647	4,217	3,900
M15	3,966	3,798	4,455	4,073
M16	3,873	3,676	4,504	4,018
M18	5,562	3,893	4,626	4,694
M20	5,044	3,692	4,320	4,352
M22	4,717	3,553	4,067	4,112
M24	4,456	3,384	4,182	4,007
M25	3,842	3,686	4,218	3,915
M26	3,690	3,400	3,801	3,630
M27	3,707	3,497	3,711	3,638
M28	3,546	3,271	3,480	3,432
M29	3,618	3,279	3,646	3,514
Average	3,958	3,563	4,029	3,850

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

Densities for marine mammals in Cook Inlet were derived from MML aerial surveys, typically flown in June,

from 2000 to 2018 (Rugh *et al.* 2005; Shelden *et al.* 2013, 2015, 2017, 2019). A survey was also conducted in 2021 but density information is not yet available. While the surveys are concentrated for a few days in June annually, which may skew densities for seasonally present species, they are still the best available long-term dataset of marine mammal sightings available in Cook Inlet. Density was calculated by summing the total number of animals observed and dividing the number sighted by the area surveyed. The total number of animals observed accounts for both lower and upper Cook Inlet. There are no density estimates available for California sea lions in Cook Inlet, as they are so infrequently sighted. Densities are presented in Table 10 below.

TABLE 10—DENSITIES OF MARINE MAMMALS IN COOK INLET

Species	Density (indiv/km^2)
Humpback whale	0.001770
Minke whale	0.000009
Gray whale	0.000075
Fin whale	0.000311
Killer whale	0.000601
Beluga whale (MML lower CI)	0.000023
Beluga whale (MML middle CI)	0.001110
Goetz beluga—LCI	0.011106
Goetz beluga—NCI	0.001664
Goetz beluga—TB	0.015053
Dall's porpoise	0.000154
Harbor porpoise	0.004386
Harbor seal	0.241401
Steller sea lion	0.007609
California sea lion	0.000000

For beluga whales, two densities were considered as a comparison of available data. The first source considered was directly from the MML aerial surveys, as described above. Sighting data collected during aerial surveys is collected and then several correction factors are applied to address perception, availability, and proximity bias. These corrected sightings totals are then divided by the total area covered during the survey to arrive at a density value. Densities were derived for the entirety of Cook Inlet as well as for middle and lower Cook Inlet. Densities across all three regions are low and there is a known effect of seasonality on the distribution of the whales. Thus, densities derived directly from surveys flown in June might underestimate the density of beluga whales in lower Cook Inlet at other ice-free times of the year.

The other mechanism for arriving at beluga whale density considered here is the Goetz *et al.* (2012) habitat-based model. This model is derived from sightings and incorporates depth soundings, coastal substrate type, environmental sensitivity index, anthropogenic disturbance, and anadromous fish streams to predict densities throughout Cook Inlet. The output of this model is a beluga density map of Cook Inlet, which predicts spatially explicit density estimates for Cook Inlet belugas. Using the resulting grid densities, average densities were calculated for two regions applicable to Hilcorp's operations. The densities applicable to the area of activity (*i.e.,* the North Cook Inlet Unit density for middle Cook Inlet activities and the Trading Bay density for activities in Trading Bay) are provided in Table 11 below and were carried forward to the exposure estimates. Likewise, when a range is given, the higher end of the range was used out of caution to calculate exposure estimates (*i.e.,* Trading Bay in the Goetz model has a range of 0.004453 to 0.015053; 0.015053 was used for the exposure estimates).

TABLE 11—COOK INLET BELUGA WHALE DENSITIES BASED ON GOETZ *et al.* (2012) HABITAT MODEL

Project location	Beluga whale density (ind/km^2)
North Cook Inlet Unit (middle Cook Inlet)	0.001664
Trading Bay Area	0.004453–0.015053

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate for each of the two IHAs.

Year 1 IHA—As described above, Hilcorp's tug towing rig activity was divided into two portions for the purpose of take estimation: Stationary and mobile activity. For stationary activity, five hours of sound production per day was assumed for up to 16 days (eight moves or segments consisting of two days each). For the mobile portion of the activity, two days of nine hours of mobile activity (assuming a source velocity of 2.06 m/s) and six days of six hours of mobile activity were assumed, for a total of eight rig moves.

Year 2 IHA—For stationary activity, 5 hours of sound production per day was assumed for up to 16 days. For mobile activity, 9 hours of sound production was assumed for 2 days, as well as 6 hours of sound production for 6 days, for a total of eight rig moves.

The ensonified areas calculated per activity type (stationary and mobile) for a single day were multiplied by marine mammal densities to get an estimate of exposures per day. This was then multiplied by the number of days of that type of activity (stationary or mobile) to arrive at the number of estimated exposures per year per activity type. These exposures by activity type were then summed to result in a number of exposures per year for all tug towing rig activity. The estimated exposures are provided below in Tables 12 and 13 for Year 1 and Year 2 of activity, respectively. The calculated exposures for Years 1 and 2 are identical, as the number of days and hours of expected tug noise is ultimately the same despite the different divisions of the activity (*e.g.* Year 1 has tug noise from P&A, Year 2 does not have P&A but has more overall tugging trips). There are two estimates for beluga whales provided in the tables below to demonstrate the difference in the calculations based on the chosen density value. As exposure estimates were calculated based on specific potential rig moves or well locations, the density value for beluga whales that was carried through the estimate was the higher density value for that particular location. There are no estimated exposures based on this method of calculation for California sea lions because the assumed density is 0.00 animals/km^2.

TABLE 12—TOTAL CALCULATED EXPOSURES FOR YEAR 1

Group	Species	Level A	Level B
LF Cetaceans	Humpback whale	0.000	4.058
	Minke whale	0.000	0.021
	Gray whale	0.000	0.171
	Fin whale	0.000	0.712
MF Cetaceans	Killer whale	0.000	1.379
	Beluga whale NMFS	0.000	2.545
	Beluga whale Goetz	0.000	10.345

TABLE 12—TOTAL CALCULATED EXPOSURES FOR YEAR 1—Continued

Group	Species	Level A	Level B
HF Cetaceans	Dall's porpoise	0.001	0.353
	Harbor porpoise	0.038	10.057
Phocids	Harbor seal	0.012	553.565
Otariids	Steller sea lion	0.000	17.448
	California sea lion	0.000	0.000

TABLE 13—TOTAL CALCULATED EXPOSURES FOR YEAR 2

Group	Species	Level A	Level B
LF Cetaceans	Humpback whale	0.000	4.058
	Minke whale	0.000	0.021
	Gray whale	0.000	0.171
	Fin whale	0.000	0.712
MF Cetaceans	Killer whale	0.000	1.379
	Beluga whale NMFS	0.000	2.545
	Beluga whale Goetz	0.000	11.651
HF Cetaceans	Dall's porpoise	0.001	0.353
	Harbor porpoise	0.038	10.057
Phocids	Harbor seal	0.012	553.565
Otariids	Steller sea lion	0.000	17.448
	California sea lion	0.000	0.000

Based on the analysis described above, NMFS does not propose to authorize take via Level A harassment related to Hilcorp's tug towing drill rig activity. For mobile tugging, the distances to the PTS thresholds for high frequency cetaceans (the only functional hearing group of concern based on the model results) are smaller than the overall size of the tug and rig configuration, making it unlikely a cetacean would remain close enough to the tug engines to incur PTS. For stationary positioning of the jack up rig, the PTS isopleths are up to 679 m for high frequency cetaceans, but calculated on the assumption that an animal would remain within several hundred meters of the jack-up rig for the full five hours of noise-producing activity. Given the location of the activity is not in an area known to be essential habitat for any marine mammal species with extreme site fidelity over the course of two days, the occurrence of PTS is unlikely. A table indicating the number of takes, by Level B harassment, proposed to be authorized is provided below.

TABLE 14—TAKES (BY LEVEL B HARASSMENT) CALCULATED AND PROPOSED TO BE AUTHORIZED FOR YEAR 1 IHA AND YEAR 2 IHA

	Year 1 calculated	Year 1 authorized	Year 2 calculated	Year 2 authorized
Humpback whale	4.058	6	4.058	6
Minke whale	0.021	6	0.021	6
Gray whale	0.171	2	0.171	2
Fin whale	0.712	4	0.712	4
Killer whale	1.379	10	1.379	10
Beluga whale	2.545 (MML) 10.345 (Goetz)	22	2.545 (MML) 11.651 (Goetz)	22
Dall's porpoise	0.353	6	0.353	6
Harbor porpoise	10.057	44	10.057	44
Harbor seal	553.565	554	553.565	554
Steller sea lion	17.448	17	17.448	17
California sea lion	0	2	0	2

As illustrated by the table above, the estimated exposures for several species are less than one. While uncommon, these species have been previously sighted in Cook Inlet and some are unlikely to appear as solitary individuals when sighted. For humpback whales, the number of takes proposed to be authorized is increased from the calculated estimate of four to six individuals. There were two sightings of three humpback whales observed near Ladd Landing north of the Forelands during the Harvest Alaska CIPL project (Sitkiewicz *et al.* 2018). Based on documented observations during the CIPL survey (the survey nearest the Action Area), Hilcorp is requesting six takes of humpback whales to allow for up to two sightings of three individuals, consistent with what was observed during the CIPL project. Minke whale takes proposed to be authorized are increased from the calculated less than one individual to five. Minke whales are commonly sighted in groups of two or three, as well as sightings of individuals. There were eight sightings of eight minke whales observed during the 2019 Hilcorp lower Cook Inlet seismic survey (Fairweather Science 2020). As the occurrence of minke whales is expected to be less in middle Cook Inlet than lower Cook Inlet and considering the observed group sizes, Hilcorp is

requesting six takes of minke whale to allow for the possibility of two sightings of a group of three individuals. During Apache's 2012 seismic program, nine gray whales were observed in June and July (Lomac-MacNair *et al.* 2013). During Apache's seismic program in 2014, one gray whale was observed (Lomac-MacNair *et al.* 2014). During SAExploration's seismic survey in 2015, the 2018 CIPL project, and Hilcorp's 2019 seismic survey, no gray whales were observed (Kendall *et al.* 2015; Sitkiewicz *et al.* 2018; Fairweather Science 2020). Considering the Action Area is in middle Cook Inlet where sightings of gray whales are less common, Hilcorp is requesting two takes of gray whales to allow for the potential occurrence of two individual gray whales. The number of fin whale takes proposed to be authorized is increased from one to four individuals, as they may be seen in groups of two to seven individuals. During seismic surveys conducted in 2019 by Hilcorp in the lower Cook Inlet, fin whales were recorded in groups ranging in size from one to 15 individuals (Fairweather 2020). During the NMFS aerial surveys in Cook Inlet from 2000 to 2018, 10 sightings of 26 estimated individual fin whales in lower Cook Inlet were observed (Shelden *et al.* 2013, 2015, 2016, 2019). A total authorized take of four fin whales would account for two sightings of two animals, which is the lower end of the range of common group size.

The number of proposed killer whale takes is increased to ten from the calculated exposure of one. Killer whales are typically sighted in pods of a few animals to 20 or more (NOAA 2022b). During seismic surveys conducted in 2019 by Hilcorp in the lower Cook Inlet, 21 killer whales were observed, either as single individuals or in groups ranging in size from two to five individuals (Fairweather 2020). Based on documented sightings, Hilcorp requests ten takes of killer whales to allow for two sightings with a group size of five individuals. Depending on the density data used for each activity, the estimated annual exposures for beluga whales is three to 10 animals. The proposed number of takes to be authorized for beluga whales is 22 animals to allow for the possibility that more than one observation of typical Cook Inlet beluga groups occurs. The 2018 MML aerial survey (Shelden and Wade, 2019) estimated a median group size of approximately 11 beluga whales, although group sizes were highly variable (two to 147 whales) as was the case in previous survey years (Boyd *et al.* 2019). Additionally, vessel-based surveys in 2019 observed beluga whale groups in the Susitna River Delta (roughly 24 km [15 miles] north of the Tyonek Platform) that ranged from 5 to 200 animals (McGuire *et al.* 2021). The very large groups seen in the Susitna River Delta are not expected near Hilcorp's platforms, however, smaller groups (*i.e.,* around the median group size) could be traveling through to access the Susitna River Delta and other nearby coastal locations, particularly in the shoulder seasons when belugas are more likely to occur in middle Cook Inlet. The number of Dall's porpoise takes proposed to be authorized is increased from less than one estimated individual to six. Dall's porpoises are usually found in groups averaging between two and 12 individuals (NOAA 2022c). During seismic surveys conducted in 2019 by Hilcorp in the lower Cook Inlet, Dall's porpoises were recorded in groups ranging in size from two to seven individuals (Fairweather 2020). The 2012 Apache survey recorded two groups of three individual Dall's porpoises (Lomac-MacNair 2014). Because occurrence of Dall's porpoise is anticipated to be less in middle Cook Inlet than lower Cook Inlet, the smaller end of documented group sizes (three individuals) is used, and Hilcorp requests six takes of Dall's porpoise to allow for two sightings of three individuals similar to the numbers observed during the 2012 Apache survey. Harbor porpoise takes are proposed to be increased from an estimated 10 takes to 44 takes. Shelden *et al.* (2014) compiled historical sightings of harbor porpoises from lower to upper Cook Inlet that spanned from a few animals to 92 individuals. The 2018 CIPL project that occurred just north of the Action Area in Cook Inlet reported 29 sightings of 44 individuals (Sitkiewicz *et al.* 2018). While the duration of days that the tugs are towing a jack-up rig will be less than the CIPL project, given the increase in sightings of harbor porpoise in recent years and the inability to shut down the tugs, Hilcorp request 44 takes of harbor porpoise, commensurate with the number observed in the nearby CIPL project.

Calculated take of California sea lions was zero because the assumed density in Cook Inlet is zero. Any potential sightings would likely be of lone out of habitat individuals. Two solitary individuals were seen during the 2012 Apache seismic survey in Cook Inlet (Lomac-MacNair *et al.* 2013). Two takes are requested based on the potential that two lone animals could be sighted over a year of work, as was seen during Apache's year of work.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

NMFS anticipates the project, in both of the two IHAs, will create an acoustic footprint above ambient sound levels of approximately 45 km^2 around the tugs positioning the jack-up rig or for approximately 7 km in all directions along a towing trajectory of approximately 37km. There is a

discountable potential for marine mammals to incur PTS from the project, as source levels are relatively low, non-impulsive, and animals would have to remain at very close distances for multiple hours to accumulate acoustic energy at levels that could damage hearing. Therefore, we do not believe there is potential for Level A harassment and there is no designated shut-down/exclusion zone proposed for this project. However, Hilcorp will implement a number of mitigation measures designed to reduce the potential for and severity of Level B harassment and minimize the acoustic footprint of the project.

The tugs towing a jack-up rig are not able to shutdown while transiting or positioning the rig. Hilcorp will maneuver the tugs towing the jack-up rig such that they maintain a consistent speed (approximately 4 knots) and avoid multiple changes of speed and direction to make the course of the vessels as predictable as possible to marine mammals in the surrounding environment, characteristics that are expected to be associated with a lower likelihood of disturbance. Hilcorp proposes to implement a clearance zone of 1,500 meters around the centerpoint of the three tug configuration and will employ two NMFS-approved protected species observers (PSOs) to conduct marine mammal monitoring for all mobile and stationary activity involving tugs towing attached to the jack-up rig. Prior to commencing activities during daylight hours or if there is a 30-minute lapse in operational activities, the PSOs will monitor the clearance zone for marine mammals for 30 minutes. If no marine mammals are observed, operations may commence. If a marine mammal(s) is observed within the clearance zone during the clearing, the PSOs will continue to watch until either: (1) The animal(s) is outside of and on a path away from the clearance zone; or (2) 15 minutes have elapsed if the species was a pinniped or small cetacean, or 30 minutes for large cetaceans whales. Once the PSOs have determined one of those conditions are met, operations may commence.

Should a marine mammal be observed during towing or positioning, the PSOs will monitor and carefully record any reactions observed until the jack-up rig has reached its intended position. No new operational activities would be started until the animal leaves the area. PSOs will also collect behavioral information on marine mammals sighted during monitoring efforts.

Hilcorp will make every effort to operate with the tide, resulting in a low power output from the tugs towing the jack-up rig. If human safety or equipment integrity is at risk, Hilcorp may necessarily operate in an unfavorable tidal state. Due to the nature of tidal cycles in Cook Inlet, it is possible the most favorable tide for the towing operation will occur during nighttime hours. Hilcorp will operate the tugs towing the jack-up rigs at night if the nighttime operations result in a lower power output from the tugs by operating with a favorable tide.

In low-light conditions, night-vision devices shown to be effective at detecting marine mammals in low-light conditions (*e.g.,* Armasight by FLIR Command Pro®, or similar) will be provided to PSOs to aid in low-light visibility. Every effort will be made to observe that the clearance zone is free of marine mammals by using night-vision devices, however it may not always be possible to see and clear the entire clearance zone prior to nighttime transport. PSOs will monitor the greatest extent feasible for 30 minutes immediately prior to the start of load bearing activities. If no marine mammals are observed, operations may commence. If a marine mammal is observed within the during the clearing, the PSOs will continue to watch until either: (1) The animal(s) is outside of and on a path away from the clearance zone; or (2) 15 minutes have elapsed if the species was a pinniped or small cetacean, or 30 minutes for large cetaceans whales. Once the PSOs have determined one of those conditions are met, operations may commence.

Out of concern for potential disturbance to Cook Inlet beluga whales in sensitive and essential habitat, Hilcorp will not conduct noise-producing activity within 16 km (10 miles) of the mean high-high water line of the Susitna River Delta (Beluga River to the Little Susitna River) between April 15 and October 15.

Based on our evaluation of the applicant's proposed measures, for both IHAs, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance and on the availability of such species or stock for subsistence uses.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas).
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors.
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks.
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat).
- Mitigation and monitoring effectiveness.

Hilcorp will abide by all monitoring and reporting measures contained within their Marine Mammal Monitoring and Mitigation Plan, dated February 25, 2022. A summary of those measures and additional requirements proposed by NMFS is provided below.

A minimum of two NMFS-approved PSOs will be on-watch during all activities wherein the jack-up rig is attached to the tugs for the duration of the project. Minimum requirements for a PSO include:

(a) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the

water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;

(b) Advanced education in biological science or related field (undergraduate degree or higher required);

(c) Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);

(d) Experience or training in the field identification of marine mammals, including the identification of behaviors;

(e) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(f) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and

(g) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

PSOs will be stationed aboard a tug or the jack-up rig, work in shifts lasting no more than four hours without a minimum of a one hour break, and will not be on-watch for more than 12 hours within a 24-hour period.

Hilcorp will submit monthly reports for all months in which tugs towing or positioning the jack-up rig occurs. A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of the tug towing jack-up rig activities for the year. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (*e.g.,* percent cover, visibility);
- Water conditions (*e.g.,* sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Locations of all marine mammal observations; and
- Other human activity in the area.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If NMFS submits comments, Hilcorp will submit a final report addressing NMFS comments within 30 days after receipt of comments.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHAs (if issued), such as an injury, serious injury or mortality, Hilcorp would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.,* Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Hilcorp to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Hilcorp would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Hilcorp discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), Hilcorp would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Hilcorp to determine whether modifications in the activities are appropriate.

In the event that Hilcorp discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHAs (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Hilcorp would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. Hilcorp would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all the species

listed in Table 15, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

To avoid repetition, this introductory section of our analysis applies to all the species listed in Table 15, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Potential impacts to marine mammal habitat were discussed previously in this document (see Potential Effects of Specified Activities on Marine Mammals and their Habitat). Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. In addition to being temporary and short in overall duration, the acoustic footprint of both years of the proposed activity is small relative to the overall distribution of the animals in the area and their use of the area. Feeding behavior is not likely to be significantly impacted, as no areas of biological significance for marine mammal feeding are known to exist in the project area and individual marine mammals are not expected to be exposed to the noise from the activities repeatedly or in long durations.

The proposed project would create an acoustic footprint around the project area for a total of sixteen days per year from approximately April through October. Noise levels within the footprint would reach or exceed 120 dB rms. We anticipate the 120 dB footprint to be limited to no more than 45km^2 around the tugs positioning the jackup rig or approximately 7 km in all directions along a towing trajectory of approximately 37 km. The habitat within the footprint is not heavily used by marine mammals during the project time frame (*e.g.,* Cook Inlet beluga whale Critical Habitat Area 2, within which the activity resulting in the take of marine mammals is anticipated to potentially occur, is designated for beluga fall and winter use) and marine mammals are not known to engage in critical behaviors associated with this portion of Cook Inlet (*e.g.,* no known breeding grounds, foraging habitat, etc.). Most animals will likely be transiting through the area; therefore, exposure would be brief. Animals may swim around the project area but we do not expect them to abandon any intended path. We also expect the number of animals exposed to be small relative to population sizes. Finally, Hilcorp will minimize potential exposure of marine mammals to elevated noise levels by not commencing operational activities if marine mammals are observed within the immediate starting area. Hilcorp is also able to reduce the impact of their activity by conducting tugging operations with favorable tides whenever feasible. In summary and as described above, the following factors primarily support our preliminary determinations that the impacts resulting from the activities described for these two IHAs are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized.
- The mobile portion of the project does not involve noise sources capable of inducing PTS in any species other than high frequency cetaceans;
- Exposure would likely be brief given transiting behavior of marine mammals in the action area;
- Marine mammal densities are low in the project area; therefore, there will not be substantial numbers of marine mammals exposed to the noise from the project compared to the affected population sizes; and
- Hilcorp would monitor for marine mammals daily and minimize exposure to operational activities.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity described in the Year 1 IHA will have a negligible impact on all affected marine mammal species or stocks. Also, separately, NMFS preliminarily finds that the total marine mammal take from the proposed activity described in the Year 2 IHA will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one third of the species or stock abundance (as it is for all stocks in both the Year 1 and Year 2 IHAs), the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 15 provides the quantitative analysis informing our small numbers determinations for the Year 1 and Year 2 IHAs. For most species, the amount of take proposed represents less than approximately two percent of the population for each IHA. For beluga whales, the amount of take proposed represents slightly under eight percent of the population for each IHA.

TABLE 15—PERCENT OF STOCK PROPOSED TO BE TAKEN BY LEVEL B HARASSMENT UNDER EACH IHA

Species	Stock	Abundance (Nbest)	Proposed take (Level B)	Percent of stock
Year 1:				
Humpback whale	Western North Pacific	11,571	6	0.05
Minke whale	Alaska	1,233	6	0.49
Gray whale	Eastern Pacific	26,960	2	0.01
Fin whale	Northeastern Pacific	2,554	4	0.16
Killer whale	Alaska Resident Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	587 2,347	10	1.7 0.43
Beluga whale	Cook Inlet	279	22	7.89

TABLE 15—PERCENT OF STOCK PROPOSED TO BE TAKEN BY LEVEL B HARASSMENT UNDER EACH IHA—Continued

Species	Stock	Abundance (Nbest)	Proposed take (Level B)	Percent of stock
Dall's porpoise	Alaska	83,400	6	0.01
Harbor porpoise	Gulf of Alaska	31,046	44	0.14
Harbor seal	Cook Inlet/Shelikof	26,907	554	2.06
Steller sea lion	Western	53,624	17	0.03
California sea lion	U.S.	233,515	5	0.00
Year 2:				
Humpback whale	Western North Pacific	11,571	6	0.05
Minke whale	Alaska	1,233	6	0.49
Gray whale	Eastern Pacific	26,960	2	0.01
Fin whale	Northeastern Pacific	2,554	4	0.16
Killer whale	Alaska Resident Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	587	10	1.7 0.43
Beluga whale	Cook Inlet	279	22	7.89
Dall's porpoise	Alaska	83,400	6	0.01
Harbor porpoise	Gulf of Alaska	31,046	44	0.14
Harbor seal	Cook Inlet/Shelikof	26,907	554	2.06
Steller sea lion	Western	53,624	17	0.03
California sea lion	U.S.	233,515	2	0.00

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks for the Year 1 IHA. Separately, NMFS also preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks for the Year 2 IHA.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses by Alaska Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

To further minimize any potential effects of their action on subsistence activities, Hilcorp has outlined their communication plan for engaging with subsistence users in their Stakeholder Engagement Plan (Appendix B of Hilcorp's application). Hilcorp will be required to abide by this plan and update the plan accordingly.

Subsistence communities identified as project stakeholders near Hilcorp's middle Cook Inlet and Trading Bay activities include the Village of Salamatof and the Native Village of Tyonek. The ADF&G Community Subsistence Information System does not contain data for Salamatof. For the purposes of our analyses for the Year 1 and Year 2 IHAs, we can assume the subsistence uses are similar to those of nearby communities such as Kenai. At 3.5 km away from the closest point of approach, Tyonek is the closest subsistence community to Hilcorp's proposed tug route. Tyonek, on the western side of lower Cook Inlet, has a subsistence harvest area that extends from the Susitna River south to Tuxedni Bay (BOEM 2016). In Tyonek, harbor seals were harvested between June and September by 6 percent of the households (Jones *et al.* 2015). Seals were harvested in several areas, encompassing an area stretching 32.2 km (20 miles) along the Cook Inlet coastline from the McArthur Flats north to the Beluga River. Seals were searched for or harvested in the Trading Bay areas as well as from the beach adjacent to Tyonek (Jones *et al.* 2015).

Subsistence hunting of whales is not known to currently occur in Cook Inlet. Hilcorp's tug towing jack-up rig activities may overlap with subsistence hunting of seals. However, these activities typically occur along the shoreline or very close to shore near river mouths, whereas most of Hilcorp's tugging is in the middle of the Inlet and rarely near the shoreline or river mouths. Any harassment to harbor seals is anticipated to be short-term, mild, and not result in any abandonment or behaviors that would make the animals unavailable to Alaska Natives.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from Hilcorp's's proposed activities under the Year 1 IHA. Separately, NMFS has also preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from Hilcorp's proposed activities under the Year 2 IHA.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the Alaska Regional Protected Resources Division Office.

NMFS is proposing to authorize take of humpback whales (Mexico DPS, Western North Pacific DPS), fin whales (Northeastern Pacific stock), beluga whales (Cook Inlet stock), and Steller

sea lion (Western DPS), which are listed under the ESA.

The Permit and Conservation Division has requested initiation of Section 7 consultation with the NMFS Alaska Region for the issuance of these two IHAs. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue two consecutive IHAs to Hilcorp for its tugs towing a jack-up rig in Cook Inlet in 2022–2023 and 2023–2024 open water seasons, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. Drafts of the proposed IHAs can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorizations, and any other aspect of this notice of proposed IHAs for the proposed tug towing jack-up rig activity. We also request at this time comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: May 4, 2022.

Kimberly Damon-Randall,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–09916 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB989]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit renewal application from the Massachusetts Division of Marine Fisheries contains all of the required information and warrants further consideration. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act and the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notice to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before May 24, 2022.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: NMFS.GAR.EFP@noaa.gov.* Include in the subject line ''Comments on MA DMF Ventless Trap EFP.'' If you cannot submit a comment through this method, please contact Allison Murphy at (978) 281–9122, or email at *allison.murphy@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Murphy, Fishery Policy Analyst, 978–281–9122, *allison.murphy@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Massachusetts Division of Marine Fisheries (MA DMF) submitted a complete application on April 8, 2022, for an Exempted Fishing Permit (EFP) to conduct a lobster abundance survey that Federal regulations would otherwise restrict. The purpose of this study is to provide fishery-independent data on lobster growth and abundance in Massachusetts state waters of statistical areas 514 and 538. This EFP would authorize up to seven vessels to conduct larval sampling in Lobster Conservation Management Area 1 and 2. A map of this area is available at: *https://www.fisheries.noaa.gov/resource/map/lobster-management-areas.*

For this project, MA DMF is requesting exemptions from the following Federal lobster regulations:

1. Gear specification requirements to allow for the use of traps without escape vents (50 CFR 697.21(c)(1) for Lobster Management Area 1 and § 697.21(c)(2) for Area 2);

2. Trap limit requirements to allow for trap limits to be exceeded (§ 697.19(a) for Area 1 and § 697.19(b) for Lobster Management Area 2);

3. Trap tag requirements to allow for alternatively-tagged traps (§ 697.19(i));

4. Minimum and maximum carapace length requirements to allow sub-legal and over-sized lobsters to be landed for research purposes (§ 697.20(a)(2) and 697.20(b)(2) for Area 1, and § 697.20(a)(3) and 697.20(b)(3) for Area 2);

5. V-notch possession requirement to allow landing of female lobsters for research purposes (§ 697.20(g)(1) for Area 1 and § 697.20(g)(3) for Area 2);

6. Berried female possession requirement to allow landing of egg-bearing female lobsters for research purposes (§ 697.20(d)(1)and(3));

7. Minimum carapace width requirements to allow sub-legal Jonah crabs to be landed for research purposes (§ 697.20(h)(1)); and

8. Berried female possession requirement to allow landing of egg-bearing female Jonah crabs for research purposes (§ 697.20(h)(2)(i) and (ii)).

This survey has occurred annually since 2006 in Massachusetts state waters. The EFP would authorize three participating vessels to deploy three standard and three ventless traps per six-pot trawl. Stations would be sampled twice per month from June through October 2022. Sampling trips would occur after a soak time of approximately 3 days and at least one MA DMF scientist would be on board for the sampling trips. MA DMF personnel would not be on board when traps are baited and deployed. All gear would be Atlantic Large Whale Take Reduction Plan compliant. Survey traps will be separate from each vessel's commercial lobster traps and would be tagged as, ''MADMF Research Traps.''

All catch during sampling trips would be retained temporarily to collect biological data. MA DMF staff may collect lobsters and/or Jonah crabs, including undersized, oversized, v-notched, and egg-bearing females. Collected samples would be used for research projects on growth and maturity. No catch from the experimental trips would be landed for sale.

If approved, MA DMF may request minor modifications and extensions to the EFP throughout the study. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: May 3, 2022.

Jennifer M. Wallace,

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

[FR Doc. 2022–09841 Filed 5–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0050]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 8, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: New Parent Support Program Evaluation; OMB Control Number 0704–NPSP.

Needs and Uses: The Military Community & Family Policy Family Advocacy Program (FAP) within the DoD's Office of the Deputy Assistant Secretary of Defense (OSD) is requesting Office of Management and Budget clearance for the New Parent Support Program (NPSP) Evaluation. OSD FAP contracted with Pennsylvania State University for this data collection to assist in understanding the benefits and limitations of using a DoD developed, standardized, evidence-informed home visitation curriculum (*i.e.,* Take Root Home Visitation [TRHV]) within the NPSP. TRHV is a tailorable home visitation curriculum that addresses risk and protective factors for child maltreatment, which is a primary focus of NPSP home visitation. TRHV is designed to be used by home visitors to structure their time with their clients and their families. TRHV helps home visitors actively work with parents to strengthen core parenting skills, improve the parent-child bond, and promote positive child development. During visits, home visitors will use TRHV to collaborate with parents on identifying areas of strength and challenge, discuss ideas and strategies that can help parents achieve their goals, engage in role play or other skill building activities to help parents master core concepts, observe parents as they interact with their child and provide feedback, provide parents with handouts and other relevant materials, and assign skill practice homework to be completed between visits.

Affected Public: Individuals or households.

Annual Burden Hours: 210 hours.

Number of Respondents: 315.

Responses per Respondent: 1.

Annual Responses: 315.

Average Burden per Response: 40 minutes.

Frequency: On occasion.

Dated: May 3, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–09859 Filed 5–6–22; 8:45 am]

BILLING CODE 5001–06–P

DENALI COMMISSION

Denali Commission Fiscal Year 2023 Draft Work Plan

AGENCY: Denali Commission.

ACTION: Notice.

SUMMARY: The Denali Commission (Commission) is an independent Federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and

training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission is required to develop an annual work plan for future spending which will be published in the **Federal Register**, providing an opportunity for a 30-day period of public review and written comment. This **Federal Register** notice serves to announce the 30-day opportunity for public comment on the Denali Commission Draft Work Plan for Federal Fiscal Year 2023 (FY 2023).

DATES: Comments and related material to be received by, June 9, 2022.

ADDRESSES: Submit comments to the Denali Commission, Attention: Elinda Hetemi, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Elinda Hetemi, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–3415. Email: *ehetemi@denali.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Denali Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to build and ensure the operation and maintenance of Alaska's basic infrastructure, and to develop a well-trained labor force employed in a diversified and sustainable economy.

By creating the Commission, Congress mandated that all parties involved partner together to find new and innovative solutions to the unique infrastructure and economic development challenges in America's most remote communities. Pursuant to the Denali Commission Act, the Commission determines its own basic operating principles and funding criteria on an annual federal fiscal year (October 1 to September 30) basis. The Commission outlines these priorities and funding recommendations in an annual work plan. The FY 2023 Work Plan was developed in the following manner.

- At a meeting of the Denali Commissioners the Commissioners voted to adopt the FY 2023 Workplan.
- The work plan was published on *Denali.gov* for review by the public in advance of public testimony.
- A public hearing was held to record public comments and recommendations on the preliminary draft work plan.
- No public comments were received.
- The Federal Co-Chair prepared the draft work plan for publication in the **Federal Register** providing a 30-day period for public review and written comment. During this time, the draft work plan will also be disseminated to Commission program partners including, but not limited to, the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), Department of Agriculture—Rural Utilities Service (USDA/RUS), and the State of Alaska.
- At the conclusion of the **Federal Register** Public comment period Commission staff will provide the Federal Co-Chair with a summary of public comments and recommendations, if any, on the draft work plan.
- If no revisions are made to the draft, the Federal Co-Chair will provide notice of approval of the work plan to the Commissioners, and forwards the work plan to the Secretary of Commerce for approval; or, if there are revisions the Federal Co-Chair provides notice of modifications to the Commissioners for their consideration and approval, and upon receipt of approval from Commissioners, forwards the work plan to the Secretary of Commerce for approval.
- The Secretary of Commerce approves the work plan.
- The Federal Co-Chair then approves grants and contracts based upon the approved work plan.

FY 2023 Appropriations Summary

The Commission has historically received federal funding from several sources. The two primary sources at this time include the Energy & Water Appropriation Bill (''base'' or ''discretionary'' funds) and an annual allocation from the Trans-Alaska Pipeline Liability (TAPL) fund. The proposed FY 2023 Work Plan assumes the Commission will receive $15,000,000 of base funds, which is the amount referenced in the reauthorization of the Commission passed by Congress in 2016 (ref: Pub. L. 114–322), and a $2,917,000 TAPL allocation based on discussions with the Office of Management and Budget (OMB). Approximately $4,000,000 of the base funds will be used for administrative expenses and non-project program support, leaving $11,000,000 available for program activities. The total base funding shown in the Work Plan also includes an amount typically available from project closeouts and other de-obligations that occur in any given year. Approximately $117,000 of the TAPL funds will be utilized for administrative expenses and non-project program support, leaving $2,800,000 available for program activities. Absent any new specific direction or limitations provided by Congress in the current Energy & Water Appropriations Bill, these funding sources are governed by the following general principles, either by statute or by language in the Work Plan itself:

- Funds from the Energy & Water Appropriation are eligible for use in all programs.
- TAPL funds can only be used for bulk fuel related projects and activities.
- Appropriated funds may be reduced due to Congressional action, rescissions by OMB, and other federal agency actions.
- All Energy & Water and TAPL investment amounts identified in the work plan, are ''up to'' amounts, and may be reassigned to other programs included in the current year work plan, if they are not fully expended in a program component area or a specific project.
- Energy & Water and TAPL funds set aside for administrative expenses that subsequently become available, may be used for program activities included in the current year work plan.

DENALI COMMISSION FY2022 FUNDING SUMMARY

Source	Available for program activities
Energy & Water Funds:	
FY 2023 Energy & Water Appropriation [1]	$11,000,000
Subtotal	11,000,000
TAPL Funds:	
FY 2023 Annual Allocation	2,800,000

DENALI COMMISSION FY2022 FUNDING SUMMARY—Continued

Source	Available for program activities
Grand Total	13,800,000

Notes:
[1] If the final appropriation is less than $15 million the Federal Co-Chair shall reduce investments to balance the FY 2022 Work Plan.

	Base	TAPL	Total
Energy Reliability and Security:			
Diesel Power Plants and Interties	$2,900,000		$2,900,000
Wind, Hydro, Biomass, Other Proven Renewables and Emerging Technologies	750,000		750,000
Audits, TA, & Community Energy Efficiency Improvements	375,000		375,000
RPSU Maintenance and Improvement Projects	900,000		900,000
Subtotal	4,925,000		4,925,000
Bulk Fuel Safety and Security:			
New/Refurbished Facilities		$1,500,000	1,500,000
Maintenance and Improvement Projects		700,000	700,000
Subtotal	0	2,200,000	2,200,000
Village Infrastructure Protection	500,000		500,000
Transportation	500,000		500,000
Sanitation:			
Village Water, Wastewater and Solid Waste	1,500,000		1,500,000
Subtotal	1,500,000		1,500,000
Health Facilities	500,000		500,000
Housing	500,000		500,000
Broadband	250,000		250,000
Workforce Development:			
Energy and Bulk Fuel		600,000	600,000
Other	1,000,000		1,000,000
Subtotal	1,000,000	600,000	1,600,000
Flexible Funding	1,325,000		1,325,000
Totals	11,000,000	2,800,000	13,800,000

Authority: Pub. L. 105–277 section 304(b)(1).

John Whittington,
General Counsel.

[FR Doc. 2022–09862 Filed 5–6–22; 8:45 am]
BILLING CODE 3300–01–P

DENALI COMMISSION

Denali Commission Infrastructure Investment and Jobs Act (IIJA) Draft Work Plan

AGENCY: Denali Commission.

ACTION: Notice.

SUMMARY: The Denali Commission (Commission) is an independent Federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and training in Alaska by delivering federal services in the most cost-effective manner possible. This **Federal Register** notice serves to announce the 30-day opportunity for public comment on the Denali Commission IIJA Draft Work Plan.

DATES: Comments and related material to be received by, June 9, 2022.

ADDRESSES: Submit comments to the Denali Commission, Attention: Elinda Hetemi, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Elinda Hetemi, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–3415. Email: *ehetemi@denali.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Denali Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to build and ensure the operation and maintenance of Alaska's basic infrastructure, and to develop a well-trained labor force employed in a diversified and sustainable economy.

On November 15, 2021 the IIJA was signed by President Biden. In the IIJA the Denali Commission was allocated $75 million. The law left it to the Commission to determine how best to spend these funds. Through a series of informational meetings the Commissioners reviewed the needs of

rural Alaska and decided to allocate the IIJA funds as follows:

—FY 2022 Workplan Amounts: In the FY 2022 Workplan the Commission noted that if additional funds became available then $5,000,000 would be allocated to Village Infrastructure Protection Program (VIP); $250,000 to Broadband and $2,000,000 for Workforce Development. The Commissioners decided to allocate $7,250,000 of the $75 million IIJA funds to these programs consistent with the FY 2022 Workplan.

—5% of the $75 million ($3.75 million) will be allocated to cover administrative costs. This amount includes 0.5% of the funds being set aside for the Inspector General.

—The remaining $64 million will be divided into a five year spend down plan in the following categories with yearly amounts of $1 million for Energy Reliability and Security; $1 million for VIP; $1 million for Workforce Development; $10 million for the Infrastructure Fund and $550,000 set aside for Emergency situations.

The Infrastruture Fund is a new process for the Commission. The Commission will use a public Funding Opportunity Announcement (FOA) to seek applications for funding projects across a wide range of program categories including Energy, Transportation, Healthcare and Community Wellness, VIP, Sanitation, Housing, Broadband, Economic Development and Workforce Development. Applications will be reviewed and ranked according to published criteria with the highest scoring applications receiving funding.

The Commission used the following process to create the IIJA Workplan:

- The Commissioners held several work sessions where they were briefed by program partners on specific program category areas to identify unmet needs in specific programs.
- At a meeting of the Denali Commissioners the Commissioners voted to adopt the IIJA Workplan.
- The work plan was published on *Denali.gov* for review by the public in advance of public testimony.
- A public hearing was held to record public comments and recommendations on the preliminary draft work plan.
- No public comments were received.
- The Federal Co-Chair prepared the draft work plan for publication in the **Federal Register** providing a 30-day period for public review and written comment. During this time, the draft work plan will also be disseminated to Commission program partners including, but not limited to, the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), Department of Agriculture—Rural Utilities Service (USDA/RUS), and the State of Alaska.
- At the conclusion of the **Federal Register** Public comment period Commission staff will provide the Federal Co-Chair with a summary of public comments and recommendations, if any, on the draft work plan.
- If no revisions are made to the draft, the Federal Co-Chair will provide notice of approval of the work plan to the Commissioners, and forwards the work plan to the Secretary of Commerce for approval; or, if there are revisions the Federal Co-Chair provides notice of modifications to the Commissioners for their consideration and approval, and upon receipt of approval from Commissioners, forwards the work plan to the Secretary of Commerce for approval.
- The Secretary of Commerce approves the work plan.
- The Federal Co-Chair then approves grants and contracts based upon the approved work plan.

FY 2022 commitments	Yearly amount	Total amount
Village Infrastructure Protection	.....	$5,000,000
Broadband	.....	250,000
Workforce Development	.....	2,000,000
Five Year Spend-down Plan:		
Energy Reliability and Security	$1,000,000	5,000,000
Village Infrastructure Protection	1,000,000	5,000,000
Workforce Development	250,000	1,250,000
Infrastruture Fund	10,000,000	50,000,000
Emergy Fund	550,000	2,750,000
Administrative Costs	750,000	3,750,000
Total	12,800,000	75,000,000

Authority: Pub. L. 105–277 section 304(b)(1).

John Whittington,

General Counsel.

[FR Doc. 2022–09861 Filed 5–6–22; 8:45 am]

BILLING CODE 3300–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0063]

Agency Information Collection Activities; Comment Request; Foreign Schools Eligibility Criteria Apply To Participate in Title IV HEA Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before July 8, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0063. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.*

Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S.

Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Foreign Schools Eligibility Criteria Apply to Participate in Title IV HEA Programs.

OMB Control Number: 1845–0105.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Individuals and Households; Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 27,578.

Total Estimated Number of Annual Burden Hours: 8,023.

Abstract: This request is for an extension of the information collection of the requirements in the policies and procedures related to the eligibility of foreign schools to apply to participate in Title IV, HEA programs that were added by the Higher Education Opportunity Act of 2008 (HEOA). The information in 34 CFR 600.54, 600.55, 600.56, and 600.57 is used by the Department during the initial review for eligibility certification, recertification and annual evaluations. These regulations help to ensure that all foreign institutions participating in the Title IV, HEA programs are meeting the minimum participation standards.

Dated: May 4, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–09920 Filed 5–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

President's Board of Advisors on Historically Black Colleges and Universities

AGENCY: President's Board of Advisors on Historically Black Colleges and Universities, Office of Undersecretary, Department of Education.

ACTION: Announcement of an open meeting.

SUMMARY: This notice sets forth the agenda for the May 24, 2022, meeting of the President's Board of Advisors on Historically Black Colleges and Universities (Board) and provides information to members of the public about how to submit written comments and request time to make oral comments at the meeting. Notice of the meeting is required by the Federal Advisory Committee Act and is intended to notify the public of its opportunity to attend.

DATES: The Board meeting will be held on May 24, 2022, from 11:00 a.m. to 5:00 p.m. E.D.T. in the Barnard Auditorium at the U.S. Department of Education, located at 400 Maryland Avenue SW, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Sedika Franklin, Associate Director/ Designated Federal Official, U.S. Department of Education, White House Initiative on Historically Black Colleges and Universities, 400 Maryland Avenue SW, Washington, DC 20204; telephone: (202) 453–5634 or (202) 453–5630, or email *sedika.franklin@ed.gov.*

SUPPLEMENTARY INFORMATION:

PBA's Statutory Authority and Function: The Board is established by 20 U.S.C. 1063e (the HBCUs Partners Act) and Executive Order 14041 (September 3, 2021) and is continued by Executive Order 14048. The Board is governed by the provisions of FACA, which sets forth standards for the formation and use of advisory committees. The purpose of the Board is to advise the President, through the White House Initiative on Historically Black Colleges and Universities, on all matters pertaining to strengthening the educational capacity of Historically Black Colleges and Universities (HBCUs).

The Board shall advise the President in the following areas: (i) Improving the identity, visibility, and distinctive capabilities and overall competitiveness of HBCUs; (ii) engaging the philanthropic, business, government, military, homeland-security, and education communities in a national dialogue regarding new HBCU programs and initiatives; (iii) improving the ability of HBCUs to remain fiscally secure institutions that can assist the Nation in in achieving its educational goals and in advancing the interests of all Americans; (iv) elevating the public awareness of, and fostering appreciation of, HBCUs; (v) encouraging public-private investments in HBCUs; and improving government-wide strategic planning related to HBCU competitiveness to align Federal resources and provide the context for decisions about HBCU partnerships, investments, performance goals, priorities, human capital development, and budget planning.

Meeting Agenda: The meeting agenda will include roll call; welcoming remarks; a review of the Board's mission and function; a discussion of the Board's strategic priorities; and group discussion. The public comment period will begin immediately following the conclusion of such discussions. There will be an allotted time for public comment.

Access to the Meeting: An RSVP is required in order to attend the meeting virtually. Submit a reservation by email to the *whirsvps@ed.gov* mailbox. RSVPs must be received by end of business on May 21, 2022. Include in the subject line of the email request ''Meeting RSVP.'' The email must include the name(s), title, organization/affiliation (if applicable), mailing address, email address, telephone number, of the person(s) requesting to attend.

Submission of requests to make an oral comment: There are two methods the public may use to provide an oral comment pertaining to the work of the Board at the May 24, 2022 meeting.

Method One: Submit a request by email to the *whirsvps@ed.gov* mailbox. Please do not send materials directly to Board members. Requests must be sent by May 21, 2022. Include in the subject line of the email request ''Oral Comment Request.'' The email must include the name(s), title, organization/affiliation, mailing address, email address,

telephone number, of the person(s) requesting to speak, and a brief summary (not to exceed one page) of the principal points to be made. All individuals submitting an advance request in accordance with this notice will be added to the public comment request list for oral comment.

Method Two: Register in-person at the meeting location on May 24, 2022. The requestor must provide his or her name, title, organization/affiliation, mailing address, email address, and telephone number. Individuals will be placed on the public comment request list and will be selected on a first-come, first-served basis. If selected, each commenter will have an opportunity to speak for three minutes.

All oral comments made will become part of the official record of the Board. Similarly, written materials distributed during oral presentations will become part of the official record of the meeting.

Submission of written public comments: The Board invites written comments, which will be read during the public comment segment of the agenda. Comments must be submitted by May 21, 2022 to the *whirsvps@ed.gov* mailbox and include in the subject line ''Written Comments: Public Comment.'' The email must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number, of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to an electronic mail message (email) or provided in the body of an email message. Please do not send material directly to the Board members.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Board website 90 days after the meeting. Pursuant to FACA, the public may also inspect the materials at 400 Maryland Avenue SW, Washington, DC, by emailing *oswhi-hbcu@ed.gov* or by calling (202) 453–5634 to schedule an appointment.

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least one week before the meeting date. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* 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 Adobe 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.

Authority: HBCUs Partners Act, Presidential Executive Order 14041, continued by Executive Order 14048.

Donna M. Harris-Aikens,

Deputy Chief of Staff for Strategy, Office of the Secretary.

[FR Doc. 2022–09919 Filed 5–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14975–000]

Lock+™ Hydro Friends Fund XXII, LLC; Notice of Surrender of Preliminary Permit

Take notice that Lock+™ Hydro Friends Fund XXII, LLC, permittee for the proposed Little Pine Creek Dam Hydropower Project, has requested that its preliminary permit be terminated. The permit was issued on December 6, 2019 and would have expired on November 30, 2023.[1] The project would have been located at the Pennsylvania Department of Conservation and Natural Resources' Little Pine Creek Dam on Little Pine Creek in Lycoming County, Pennsylvania.

The preliminary permit for Project No. 14975 will remain in effect until the close of business, June 2, 2022. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

[1] 169 FERC ¶ 62,138 (2019).

[2] 18 CFR 385.2007(a)(2) (2021).

Dated: May 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09900 Filed 5–6–22; 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 Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–54–000.

Applicants: Southwest Power Pool, Inc.

Description: Petition for Declaratory Order and Request for Expeditious Action of Southwest Power Pool, Inc.

Filed Date: 4/21/22.

Accession Number: 20220421–5093.

Comment Date: 5 p.m. ET 5/23/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1520–007; ER10–1521–007; ER10–1522–006; ER20–2493–002.

Applicants: OTCF, LLC, Chemical Corporation, Occidental Power Marketing, L.P., Occidental Power Services, Inc.

Description: Notice of Non-Material Change in Status of Occidental Power Marketing, L.P., et al.

Filed Date: 4/29/22.

Accession Number: 20220429–5707.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–1595–016; ER10–1598–016; ER10–1616–016; ER10–1618–016; ER10–2783–018; ER10–2798–017; ER10–2799–017; ER10–2878–017; ER10–2878–018; ER10–2879–017; ER10–2960–014; ER10–2969–018; ER18–1821–008; ER18–2418–006; ER19–1738–004; ER19–2231–005; ER19–2232–005; ER21–2423–005; ER21–2424–005; ER22–40–002; ER22–46–004; ER22–1402–001; ER22–1404–001; ER22–1449–001; ER22–1450–001.

Applicants: GB II New Haven LLC, GB II Connecticut LLC, Parkway Generation Operating LLC, Parkway Generation Keys Energy Center LLC, Parkway Generation Essex, LLC, PSEG Power New York Inc., Generation Bridge M&M Holdings, LLC, Generation Bridge Connecticut Holdings, LLC, Chief Keystone Power II, LLC, Chief Conemaugh Power II, LLC, PSEG Fossil Sewaren Urban Renewal LLC, Great River Hydro, LLC, Walleye Power, LLC, Oswego Harbor Power LLC, Astoria Generating Company, L.P., Montville

Power LLC, Middleton Power LLC, Devon Power LLC, Connecticut Jet Power LLC, Arthur Kill Power LLC, Rolling Hills Generating, L.L.C., New Covert Generating Company, LLC, Lincoln Generating Facility, LLC, Crete Energy Venture, LLC.

Description: Notice of Change in Status of Crete Energy Venture, LLC, et al.

Filed Date: 4/29/22.

Accession Number: 20220429–5710.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–1818–030; ER10–1819–033; ER10–1820–036.

Applicants: Northern States Power Company, a Wisconsin corporation, Northern States Power Company, a Minnesota corporation, Public Service Company of Colorado.

Description: Notice of Change in Status of Public Service Company of Colorado, et al.

Filed Date: 4/29/22.

Accession Number: 20220429–5706.

Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–1910–025; ER10–1911–025.

Applicants: Duquesne Power, LLC, Duquesne Light Company.

Description: Notice of Change in Status of Duquesne Light Company, et al.

Filed Date: 5/2/22.

Accession Number: 20220502–5384.

Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER17–1794–005.

Applicants: Innovative Solar 42, LLC.

Description: Notice of Change in Status of Innovative Solar 42, LLC.

Filed Date: 5/2/22.

Accession Number: 20220502–5385.

Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER22–1423–001.

Applicants: Appalachian Power Company.

Description: Tariff Amendment: OATT—Kentucky Power Removal—Errata to be effective 12/31/9998.

Filed Date: 5/3/22.

Accession Number: 20220503–5177.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1786–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2022–05–03 PSCoM–NITSA–463–Amnd 2 to be effective 7/2/2022.

Filed Date: 5/3/22.

Accession Number: 20220503–5073.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1787–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Rate Schedule FERC No. 342 and Request for Expedited Action to be effective 5/31/2022.

Filed Date: 5/3/22.

Accession Number: 20220503–5087.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1788–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: Compliance filing: Order No. 676–J First Compliance to be effective 12/31/9998.

Filed Date: 5/3/22.

Accession Number: 20220503–5096.

Comment Date: 5 p.m. ET 5/24/22.

Docket Numbers: ER22–1789–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Tri-State NITSA Rev 11 to be effective 5/1/2022.

Filed Date: 5/3/22.

Accession Number: 20220503–5108.

Comment Date: 5 p.m. ET 5/24/22.

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: May 3, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09906 Filed 5–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14980–000]

Lock+™ Hydro Friends Fund XXVIII, LLC; Notice of Surrender of Preliminary Permit

Take notice that Lock+™ Hydro Friends Fund XXVIII, LLC, permittee for the proposed Nockamixon Dam Hydropower Project, has requested that its preliminary permit be terminated. The permit was issued on January 7, 2020 and would have expired on December 31, 2023.[1] The project would have been located at the Pennsylvania Department of Conservation and Natural Resources' Nockamixon Dam on Tohickon Creek in Bucks County, Pennsylvania.

The preliminary permit for Project No. 14980 will remain in effect until the close of business, June 2, 2022. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

Dated: May 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09898 Filed 5–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2934–036]

New York State Electric & Gas Corporation; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for temporary amendment of Article 402.

b. *Project No.:* 2934–036.

c. *Date Filed:* April 21, 2022, and supplemented April 28, 2022.

d. *Applicant:* New York State Electric & Gas Corporation.

e. *Name of Project:* Upper Mechanicville Hydroelectric Project.

f. *Location:* The project is located on the Hudson River in Saratoga and Rensselaer counties, New York. The project does not occupy federally owned lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* David W. Dick, New York State Electric & Gas Corporation, 89 East Avenue, Rochester, NY 14649, (585) 315–0705, *david_dick@rge.com.*

i. *FERC Contact:* Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* June 2, 2022.

[1] 170 FERC ¶ 62,007 (2020).

[2] 18 CFR 385.2007(a)(2) (2021).

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2934–036. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant proposes to temporarily amend Article 402 of the license to allow for the drawdown of the impoundment elevation. The drawdown is necessary for the licensee to replace the rubber dam components at the project. In particular, the licensee requests a temporary amendment of Article 402 to maintain the impoundment elevation at up to 12 inches below the spillway crest (65.6 feet National Geocentric Vertical Datum 1929) unless otherwise directed by the New York State Canal Corporation until the completion of the replacement and upgrade of the remaining bladders. The licensee anticipates the drawdown to occur between mid-June to mid-October 2022. The licensee would continue to operate the project in run-of-river mode except to satisfy navigation requests and provide the seasonal minimum bypass flow requirements below the project except during periods when the impoundment elevation is lower than the sill of the sluice gate.

l. *Locations of the Application:* This filing 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. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: May 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09901 Filed 5–6–22; 8:45 am]

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: RP22–897–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 5–2–22 to be effective 5/1/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5103.
Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–899–000.
Applicants: DTM Birdsboro Pipeline, LLC.
Description: Compliance filing: Cost and Revenue Study Compliance Filing.
Filed Date: 5/2/22.
Accession Number: 20220502–5246.
Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–900–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cabot Oil Name Change to Coterra Energy, Inc. Agmt No. 161137–4 to be effective 5/2/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5249.
Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–901–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—Vitol 860536 to be effective 5/1/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5250.
Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–902–000.
Applicants: Millennium Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cabot to Coterra Name Change—Agmt 151457 to be effective 5/2/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5252.
Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–903–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—CNX Gas to Spire Release to be effective 5/1/2022.

Filed Date: 5/2/22.
Accession Number: 20220502–5258.
Comment Date: 5 p.m. ET 5/16/22.
Docket Numbers: RP22–904–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 5–1–22 to be effective 5/1/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5266.
Comment Date: 5 p.m. ET 5/16/22.
Docket Numbers: RP22–905–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 5–1–22 to be effective 5/1/2022.
Filed Date: 5/3/22.
Accession Number: 20220503–5014.
Comment Date: 5 p.m. ET 5/16/22.

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.

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: May 3, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09907 Filed 5–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14976–000]

Lock+™ Hydro Friends Fund XXIII, LLC; Notice of Surrender of Preliminary Permit

Take notice that Lock+™ Hydro Friends Fund XXIII, LLC, permittee for the proposed George B. Stevenson Dam Hydropower Project, has requested that its preliminary permit be terminated. The permit was issued on December 6, 2019 and would have expired on November 30, 2023.[1] The project would have been located at the Pennsylvania Department of Conservation and Natural Resources' George B. Stevenson Dam on First Fork Sinnemahoning Creek in Cameron County, Pennsylvania.

The preliminary permit for Project No. 14976 will remain in effect until the close of business, June 2, 2022. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

Dated: May 3, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–09899 Filed 5–6–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL—9773–01–OA]

Notification of a Public Meeting of the Chartered Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public meeting of the chartered Science Advisory Board. The purpose of the meeting is to (1) review the scientific and technical basis of the proposed rule ''Revised Definition of Waters of the United States''; and (2) discuss recommendations received from the SAB Work Group for Review of Science Supporting EPA Decisions.

DATES: The public meeting of the chartered Science Advisory Board will be held on Tuesday, May 31, 2022, from 12:00 p.m. to 5:00 p.m. (Eastern Time) and Thursday, June 2, 2022, from 12:00 p.m. to 5:00 p.m. (Eastern Time).

ADDRESSES: The meeting will be conducted virtually. Please refer to the SAB website at *https://sab.epa.gov* for information on how to attend the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this notice may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), via telephone (202) 564–2155, or email at *armitage.thomas@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 (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the EPA Administrator on the scientific and 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 chartered Science Advisory Board will hold a public meeting to review the scientific and technical basis of the proposed rule ''Revised Definition of Waters of the United States'' described in 86 FR 69372—69450 and discuss recommendations received from the SAB Work Group for Review of Science Supporting EPA Decisions. Under the SAB's authorizing statute, the SAB ''may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis'' of proposed rules. The SAB Work Group for Review of Science Supporting EPA Decisions is charged with identifying EPA planned actions that may warrant SAB review. The SAB will hold a public meeting to (1) review the scientific and technical basis of the proposed rule ''Revised Definition of Waters of the United States,'' and (2) discuss recommendations received from the SAB Work Group for Review of Science Supporting EPA Decisions with regard to SAB review of other EPA planned actions.

Availability of Meeting Materials: All meeting materials, including the agenda will be available on the SAB web page 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

[1] 169 FERC ¶ 62,139 (2019).

[2] 18 CFR 385.2007(a)(2) (2021).

independent advice to the EPA. Members of the public can submit relevant comments pertaining to the committee's charge or meeting materials. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should follow the instruction below to submit comments.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to three minutes. Each person making an oral statement should consider providing written comments as well as the oral statement so that the points presented orally can be expanded upon in writing. Persons interested in providing oral statements should contact the DFO, in writing (preferably via email) at the contact information noted above by May 24, 2022, to be placed on the list of registered speakers.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by SAB members, statements should be submitted to the DFO by May 24, 2022, for consideration at the public meeting on May 31, 2022, and June 2, 2022. Written statements should be supplied to the DFO at the contact information above via email. 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 the DFO, at the contact information noted above, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Thomas H. Brennan,

Director, Science Advisory Board Staff Office.

[FR Doc. 2022–09874 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2020–0682; FRL–9826–01–ORD]

Notice of Public Comment Period on the Pool of Candidate Peer Reviewers for the Biofuels and the Environment: Third Triennial Report to Congress

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 15-day public comment period on the pool of twenty (20) candidates for the external peer review of the Biofuels and the Environment: Third Triennial Report to Congress (RtC3). The peer review will be conducted under the framework of EPA's Scientific Integrity Policy (*https://www.epa.gov/sites/default/files/2014-02/documents/scientific_integrity_policy_2012.pdf*) and follow procedures established in EPA's Peer Review Handbook 4th Edition, 2015 (EPA/100/B–15/001). After consideration of public comments on the candidate pool, EPA's contractor, ERG, will select from this pool the final list of up to nine (9) peer reviewers, ensuring their combined expertise best spans the following disciplines: Economics, engineering, agronomics, land use change, remote sensing, air quality, biogeochemistry, water quality, hydrology, conservation biology, limnology, and ecology. This **Federal Register** notice (FRN) follows a previous FRN seeking nominations for the peer review panel published on February 1, 2022.

DATES: The 15-day public comment period on the list of proposed peer review candidates begins May 9, 2022 and ends May 24, 2022. Comments must be received on or before May 24, 2022.

ADDRESSES: Please follow the instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Questions concerning the process for forming the peer review panel should be directed to EPA's contractor, ERG, by email to *peerreview@erg.com* (subject line: RtC3 Peer Review). For information on the period of submission, contact the ORD Docket at the EPA Headquarters Docket Center; phone: 202–566–1752; fax: 202–566–9744; or email: *ord.docket@epa.gov.* For technical information, contact Christopher Clark; phone: 202–564–4183; or email: *Clark.Christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Document

In 2007, Congress enacted the Energy Independence and Security Act (EISA) with the stated goals of ''mov[ing] the United States toward greater energy independence and security [and] to increase the production of clean renewable fuels.'' In accordance with these goals, EISA revised the Renewable Fuel Standard (RFS) Program, which was created under the 2005 Energy Policy Act and is administered by the EPA, to increase the volume of renewable fuel required to be blended into transportation fuel to 36 billion gallons per year by 2022. Section 204 of EISA directs the EPA, in consultation with the U.S. Departments of Agriculture and Energy, to assess and report triennially to Congress on the environmental and resource conservation impacts of the RFS Program.

The first report to Congress (RtC1) was completed in 2011 and provided an assessment of the environmental and resource conservation impacts associated with increased biofuel production and use (EPA/600/R–10/183F). The overarching conclusions of this first report were: (1) The environmental impacts of increased biofuel production and use were likely negative but limited in impact; (2) there was a potential for both positive and negative impacts in the future; and (3) EISA goals for biofuels production could be achieved with minimal environmental impacts if best practices were used and if technologies advanced to facilitate the use of second-generation biofuel feedstocks (corn stover, perennial grasses, woody biomass, algae, and waste).

The second report to Congress (RtC2) was completed in 2018 and reaffirmed the overarching conclusions of the RtC1 (EPA/600/R–18/195). The RtC2 noted that the biofuel production and use conditions that led to the conclusions of the RtC1 had not materially changed, and that the production of biofuels from cellulosic feedstocks anticipated by both the EISA and the RtC1 had not materialized. Noting observed increases in acreage for corn and soybean production in the period prior to and following implementation of the RFS2 Program, the RtC2 concluded that the environmental and resource conservation impacts associated with land use change were likely due, at least in part, to the RFS Program and associated production of biofuel feedstocks but that further research was needed.

This RtC3 builds on the previous two reports and provides an update on the impacts to date of the RFS Program on the environment. This report assesses air, water, and soil quality; ecosystem health and biodiversity; and other effects. This third report also includes new analyses not previously included in the first and second reports.

II. Information About This Peer Review

EPA's contractor, ERG, is considering a list of candidates from which to select the independent, external, peer review panel for the RtC3. On February 1, 2022, EPA announced through an FRN (87 FR 5479; FRL–9518–01–ORD) that it was seeking nominations for the peer review panel. After considering nominations submitted by the public in response to that FRN (FRL–9518–01–ORD), ERG has identified a pool of twenty (20) candidates whose combined expertise spans the following disciplines: Economics, engineering, agronomics, land use change, remote sensing, air quality, biogeochemistry, water quality, hydrology, conservation biology, limnology, and ecology. The List of Candidates (LoC) document has been posted to the docket at *https://www.regulations.gov* (EPA–HQ–ORD–2020–0682) and is included below. After review and consideration of public comments on the candidates submitted in response to this FRN, ERG will select up to nine (9) peer reviewers from this pool in a manner consistent with EPA's Peer Review Handbook 4th Edition, 2015 (EPA/100/B–15/001) based on the following factors: (1) Demonstrated expertise in the areas listed above through relevant peer-reviewed publications; (2) professional accomplishments and recognition by professional societies; (3) demonstrated ability to work constructively and effectively in a committee setting; (4) absence of conflicts of interest; (5) no appearance of a lack of impartiality; (6) willingness to commit adequate time for a thorough review of the draft report, including preparation of individual written comments that will be made publicly available; and (7) availability to participate virtually in a public two-day or three-day peer review meeting and to provide subsequent revised individual comments. ERG will independently conduct a conflict of interest (COI) screening of candidates to ensure that the selected experts have no COI in conducting this review. EPA will announce the final peer review panel, peer review meeting information, and public comment period on the RtC3 External Review Draft in a subsequent FRN. Comments on the peer review candidates must be submitted to the docket by May 24, 2022.

1. Jacob N. Barney, Virginia Tech
2. Steven T. Berry, Yale University
3. Sarah C. Davis, Ohio University
4. Bernard A. Engel, Purdue University
5. Jason D. Hill, University of Minnesota
6. S. Kent Hoekman, Desert Research Institute
7. Atul K. Jain, University of Illinois at Urbana-Champaign
8. Stephen R. Kaffka, University of California, Davis
9. Mary Kombolias, Agrafa Solutions LLC
10. Lyubov A. Kurkalova, North Carolina Agricultural and Technical State University
11. Tyler J. Lark, University of Wisconsin-Madison
12. Ruopi Li, Southern Illinois University, Carbondale
13. Chris Malins, Cerulogy Consulting, UK
14. Nathan Parker, Arizona State University
15. John M. Reilly, Massachusetts Institute of Technology
16. Timothy D. Searchinger, Princeton University
17. Aaron Smith, University of California, Davis
18. Yang Song, University of Arizona
19. Farzad Taheripour, Purdue University
20. Bin Yang, Washington State University, Tri-Cities

III. How To Submit Technical Comments to the Docket at *www.regulations.gov*

We encourage the public to submit comments to Docket ID No. [EPA–HQ–ORD–2020–0682] via web at *https://www.regulations.gov/* or via email at *ord.docket@epa.gov,* as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal Holidays. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

Instructions: Direct your comments to Docket ID No. [EPA–HQ–ORD–2020–0682]. Please ensure that your comments are submitted within the specified comment period. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at *www.regulations.gov,* including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD–ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EPA's Docket Center homepage at *www.epa.gov/epahome/dockets.htm.*

Docket: Documents in the docket are listed in the *www.regulations.gov* index. 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 materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the ORD Docket in EPA's Headquarters Docket Center.

Dated: May 3, 2022.

Wayne Cascio,

Director, Center for Public Health and Environmental Assessment, Office of Research and Development.

[FR Doc. 2022–09873 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2021–0015; FRL–9717–01–OCSPP]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrant and accepted by the Agency, of the products listed in Table 1 of Unit II, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a September 1, 2021, **Federal Register** Notice of Receipt of Requests from the registrant listed in Table 2 of Unit II to voluntarily cancel these product registrations. In the September 1, 2021, notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 180-day comment period that would merit its further review of these requests, or unless the registrant withdrew their request. The Agency did not receive any comments on the notice. Further, the registrant did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0015, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (202) 566–1744.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellation, as requested by the registrant, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
228–564	228	Brazen Herbicide	Clopyralid, monoethanolamine salt & Triclopyr, triethylamine salt.
71368–103	71368	NUP–12060	Flumioxazin.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

TABLE 2—REGISTRANT OF CANCELLED PRODUCTS

EPA company No.	Company name and address
228	NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
71368	NuFarm, Inc., Agent Name: NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Suite 101, Morrisville, NC 27560.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the September 1, 2021, **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations of the products listed in Table 1 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations of the registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II are canceled. The effective date of the cancellations that are the subject of this notice is May 9, 2022.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of September 1, 2021 (83 FR 49023) (FRL–8820–01–OCSPP). The comment period closed on February 28, 2022.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States, and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provision for the products subject to this order is as follows.

For voluntary cancellations, listed in Table 1, the registrants may continue to sell and distribute existing stocks of products listed in Table 1 until May 9, 2023, which is 1 year after publication of this cancellation order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products listed in Table 1 of Unit II until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 25, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022–09909 Filed 5–6–22; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2022–3007]

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.

This form will enable EXIM to make a credit decision on a foreign buyer credit limit request submitted by a new or existing policy holder. Additionally, this form is used by those EXIM policy holders granted delegated authority to commit the Bank to a foreign buyer credit limit.

DATES: Comments should be received on or before June 8, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 99–14) or by email to Steven Dell'Acqua *steven.dell'acqua@exim.gov,* Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The form can be viewed at *http://www.exim.gov/sites/default/files/pub/pending/eib99-14.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Steven Dell'Acqua *steven.dell'acqua@exim.gov.* 202–565–3696

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 99–14 Export-Import Bank Trade Reference form.

OMB Number: 3048–0042.

Type of Review: Renew.

Need and Use: This form provides essential credit information used by EXIM credit officers when analyzing requests for export credit insurance/financing support, both short-term (360 days and less) and medium-term (longer than 360 days), for the export of their U.S. goods and services. Additionally, this form is an integral part of the short term Multi-Buyer export credit insurance policy for those policy holders granted foreign buyer discretionary credit limit authority (DCL). Multi-Buyer policy holders given DCL authority may use this form as the sole source or one piece among several sources of credit information for their internal foreign buyer credit decision which, in turn, commits EXIM's insurance. This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635 (a) (1), to determine whether or not a company has a good payment history.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 6,500.

Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 1,625 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing time per year: 1,625 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $69,062 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $82,875.

Bassam Doughman,

IT Specialist.

[FR Doc. 2022–09865 Filed 5–6–22; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2022–3008]

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. Financial institutions interested in becoming an Approved Finance Provider (AFP) with EXIM must complete this application in order to obtain approval to make loans under EXIM insurance policies and/or enter into one or more Master Guarantee Agreements (MGA) with EXIM.

DATES: Comments must be received on or before July 11, 2022 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 10–06) or by email to Donna Schneider *donna.schneider@exim.gov,* Export-Import Bank, 811 Vermont Ave. NW, Washington, DC 20571.

The information collection tool can be reviewed at: *http://exim.gov/sites/default/files/pub/pending/eib10_06.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider *donna.schneider@exim.gov.* 202–565–3612

SUPPLEMENTARY INFORMATION: An AFP may participate in the Medium-Term Insurance, Bank Letter of Credit, and Financial Institution Buyer Credit programs as an insured lender, while AFPs approved for an MGA may apply for multiple loan or lease transactions to be guaranteed by EXIM.

EXIM uses the information provided in the form and the supplemental information required to be submitted with the form to determine whether the lender qualifies to participate in its lender insurance and guarantee programs. The details are necessary to evaluate whether the lender has the capital to fund potential transactions, proper due diligence procedures, and the monitoring capacity to carry out transactions.

Title and Form Number: EIB 10–06 Application for Approved Finance Provider.

OMB Number: 3048–0032.

Type of Review: Renew.

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: 50.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 25 hours.

Frequency of Reporting of Use: On occasion.

Government Expenses:

Reviewing time per year: 25 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $1,062.50 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $1,275.

Bassam Doughman,

IT Specialist.

[FR Doc. 2022–09868 Filed 5–6–22; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 10 a.m. on Thursday, May 5, 2022.

PLACE: The meeting was held in the FDIC Board Room, 550 17th St. NW, Washington, DC, and was webcast to the public.

MATTER TO BE CONSIDERED: Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors met in open session at 10 a.m. on Thursday, May 5, 2022 to consider the following matter:

Discussion Agenda: Memorandum and resolution re: Notice of Proposed Rulemaking on Revisions to the Community Reinvestment Act Regulations.

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Debra A. Decker, Executive Secretary of the Corporation, at 202–898–8748.

Dated at Washington, DC, on May 5, 2022.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–10016 Filed 5–5–22; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, May 12, 2022 at 10:00 a.m.

PLACE: *Hybrid Meeting:* 1050 First Street NE, Washington, DC (12th Floor) and virtual.

Note: For those attending the meeting in person, current Covid–19 safety protocols for visitors, which are based on the CDC Covid–19 community level in Washington, DC, will be updated on the Commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/*. If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the Covid–19 community level and corresponding health and safety procedures. To access the meeting virtually, go to the Commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Initial Determination on Eligibility to Receive Primary Election Public Funds—Howie Hawkins, Howie Hawkins 2020 (LRA 1132)

Audit Division Recommendation Memorandum on the Association for Emergency Responders and Firefighters, PAC (A19–21)

Audit Division Recommendation Memorandum on the US Veterans Assistance Foundation, PAC (A19–06)

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2022–10010 Filed 5–5–22; 4:15 pm]

BILLING CODE 6715–01–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 June 8, 2022.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Palm Grove Bancorp, Inc., Bussey, Iowa;* to become a bank holding company by acquiring State Bank of Bussey, Bussey, Iowa.

2. *Longview Capital Corporation, Newman, Illinois;* to acquire The Farmers Bank of Mt. Pulaski, Mt. Pulaski, Illinois.

Board of Governors of the Federal Reserve System, May 4, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–09931 Filed 5–6–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Structure Reporting and Recordkeeping Requirements for Domestic and Foreign Banking Organizations (FR Y–6, FR Y–7, FR Y–10, and FR Y–10E; OMB No. 7100–0297).

DATES: Comments must be submitted on or before July 8, 2022.

ADDRESSES: You may submit comments, identified by FR Y–6, FR Y–7, FR Y–10 and FR Y–10E, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number or FR number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collections

Collection titles: Annual Report of Holding Companies; Annual Report of Foreign Banking Organizations; Report of Changes in Organizational Structure; Supplement to the Report of Changes in Organizational Structure.

Collection identifiers: FR Y–6; FR Y–7; FR Y–10; and FR Y–10E.

OMB control number: 7100–0297.

Frequency: FR Y–6: Annual; FR Y–7: Annual; FR Y–10: Event-generated; [1] FR Y–10E: Event-generated.[2]

Respondents: Bank holding companies (BHCs), savings and loan holding companies (SLHCs), securities holding companies, and intermediate holding companies (IHCs) (collectively, holding companies (HCs)), foreign banking organizations (FBOs), state member banks that are not controlled by an HC, Edge and agreement corporations that are not controlled by a member bank, a domestic HC, or an FBO, and nationally chartered banks that are not controlled by a BHC or an FBO (with regard to their foreign investments only).

Estimated number of respondents: FR Y–6: 3,803; FR Y–7: 236; FR Y–10: 3,950; FR Y–10E: 3,950.

Estimated average hours per response:

Reporting

FR Y–6: 2.5; FR Y–7: 3; FR Y–10: 2.5; FR Y–10E: 0.5.

Recordkeeping

FR Y–6: 0.5; FR Y–10: 0.5.

Estimated annual burden hours:

Reporting

FR Y–6: 9,508; FR Y–7: 708; FR Y–10: 33,253; FR Y–10E: 1,975.

Recordkeeping

FR Y–6: 1,902; FR Y–10: 6,651.

General description of report: The FR Y–6 is filed by all top-tier HCs and non-qualifying FBOs. The report collects an organizational chart and annual

[1] In 2020, there were 13,301 FR Y–10's processed for the 3,950 reporting institutions. This volume yields an approximate annual frequency of 3.37.

[2] The FR Y–10E is event-generated and the data are submitted on an ad-hoc basis as needed.

verification of domestic branches within the organization and includes information on the identity, percentage ownership, and business interests of principal shareholders, directors, and executive officers. The FR Y–6 can be filed via a paper or electronic (Portable Document Format) submission to the appropriate Federal Reserve Bank.

The FR Y–7 is an annual report filed by qualifying FBOs that have a U.S. banking presence. The report collects financial statements, organizational information, shares and shareholder information, and data on the eligibility to be a qualified FBO as defined by the Board's Regulation K. The FR Y–7 can be filed via a paper submission mailed to the appropriate Federal Reserve Bank.

The FR Y–10 is an event-generated information collection that captures changes in organizational structure or the regulated investments and activities of various entities. The FR Y–10 can be filed electronically or via a paper, email, or fax submission to the appropriate Federal Reserve Bank.

The FR Y–10E is a free-form supplement to the FR Y–10 that the Board uses to collect additional structural information as needed on an emergency basis. Responses for the FR Y–10E are voluntary. Submission methods vary depending on the nature and time-sensitivity of the data requests.

Proposed revisions: The Board proposes to (1) revise the FR Y–6 reporting requirements for reporters who do not have any changes from their prior year's submission, (2) revise the FR Y–6 to automate and add a standard template for reporting item three, securities holders, and item four, insiders, (3) revise the FR Y–6 and FR Y–7 instructions for how the organizational chart and the tiered structure information are reported, (4) revise the FR Y–7 instructions to require the top tier FBO to file for its subsidiary FBOs, (5) revise the FR Y–6 instructions for how branches of domestic depository institutions and Edge and agreement corporations are verified and reconciled, (6) revise the FR Y–7 instructions language requirements for submission of the annual report to shareholders, (7) revise the FR Y–10 definition of control in the Glossary section of the instructions, (8) revise the FR Y–10 instructions for the legal authority codes and terminology for unitary savings and loans holding company activities that meet the requirements of section 10(c)(9)(C) of the Home Owners' Loan Act (HOLA), (9) revise the FR Y–10 instructions to update descriptions for legal authority codes 14, 68 and 999, (10) revise the FR Y–10 reporting form to add an election to become a Covered Savings Association (CSA) as a reportable event, (11) revise the FR Y–10 instructions to remove savings associations from the definition of nonbanking company, (12) clarify the FR Y–10 instructions for the definition of a head office location, (13) clarify the FR Y–10 instructions for the state of incorporation for federally chartered entities, (14) revise the FR Y–6 and the FR Y–10 instructions to add a requirement that respondents keep a record of the data submitted, and (15) make other minor clarifications and conforming edits to the FR Y–6, FR Y–7, and FR Y–10 forms and instructions. The proposed effective dates are as follows:

December 31, 2022:

- Revise the FR Y–6 reporting requirements for reporters who do not have any changes from their prior year's submission.

December 31, 2024:

- Revise the FR Y–6 to automate and add a standard template for reporting item three, securities holders, and item four, insiders.
- Revise the FR Y–6 and FR Y–7 instructions for how the organizational chart and the tiered structure information are reported.
- Revise the FR Y–6 instructions for how branches of domestic depository institutions and Edge and agreement corporations are verified and reconciled.

All other changes are proposed to be effective September 30, 2022. There are no changes proposed to the FR Y–10E.

FR Y–6 Reporting Requirements for Reporters Without Changes

The Board proposes to revise the FR Y–6 instructions and report form cover page to add a ''Yes/No'' checkbox for reporters to indicate whether the firm had changes to any reportable items from the prior year's submission. In addition, the Board proposes to add a ''Yes/No'' checkbox to items 2, 3 and 4 for reporters to specifically indicate the item(s) that changed. Currently, all HCs are required to file the full FR Y–6 report no later than 90 calendar days after their fiscal year-end. Under this proposal, reporters that check ''Yes'' for having changes to any reportable items would also check ''Yes'' for the specific item(s) that changed and submit this information as part of their FR Y–6 submission for the year. Reporters that check ''No'' for not having reportable changes would only be required to submit the signed cover page annually, along with a copy of their annual report to shareholders if they meet the reporting criteria for its submission. These revisions would reduce reporting burden for HCs that do not have changes to reportable items in a given year.

FR Y–6 Reporting for Securities Holders and Insiders

The Board proposes to revise the FR Y–6 report form and instructions to add a standard template for reporting item 3, securities holders, and item 4, insiders, and to add electronic submission of these items. Currently, HCs submit a listing of their securities holders and insiders information. The format varies by HC, given that the volume of reportable information is based on the size and complexity of the reporter. Standardizing these items simplifies reporting this information and allows for electronic submission in lieu of paper or PDF filing. In addition, electronic filing facilitates easier data submission and faster processing and provides ready accessibility of prior filings.

FR Y–6 and FR Y–7 Organization Chart

The Board proposes to revise item 2.a, Organization Chart, of the FR Y–6 and FR Y–7 to modify how reporters submit their organization chart. Under the proposal, reporters would no longer be required to submit a hard copy of their organization chart. The Board proposes to implement an electronic system for reporters to access their organization chart securely and reconcile their structure data. The revised instructions would remind reporters that, if they had any organizational changes that should have been reported previously, they would be required to submit an FR Y–10.

FR Y–6 and FR Y–7 Tiered Structure Page

The Board proposes to remove the FR Y–6 and FR Y–7 tiered structure page. As described above on the changes for item 2.a, Organization Chart, reporters would access their tiered structure in a secure system to reconcile any discrepancies.

FR Y–7 Reporter in a Multi-Tiered Organization

The Board proposes to revise the FR Y–7 instructions to require the top tier FBO to file for its subsidiary FBOs. This will reduce confusion as to which FBO would be filing in a multi-tiered organization and ensure that information reported is appropriately captured under the ultimate parent FBO.

FR Y–6 Domestic Branch Listing

The Board proposes to decommission the branch verification website, listed in item 2.b of the FR Y–6. As described

above on the changes for item 2.a, Organization Chart, reporters would access their domestic depository institutions and their branches and Edge and agreement corporations in a secure system to reconcile any discrepancies.

FR Y–7 Annual Report to Shareholders

The Board proposes to revise the FR Y–7 instructions to require the annual report to be submitted in English only. Currently, FBOs that prepare an annual report for their shareholders are required to submit a copy in the original language and an English translation copy for each reported FBO. This proposed change would result in a small burden reduction for respondents who prepare an annual report in languages other than English.

FR Y–10 Glossary—Definition of Control

The Board proposes to revise the definition of control in the FR Y–10 Glossary to be in line with the Board's final rule on control [3] and other Board forms. This proposed change would provide clarity to respondents when determining what constitutes control.

FR Y–10 Legal Authority Code and Terminology for HOLA Section 10(c)(9)(C)

The Board proposes to update the FR Y–10 to refer to unitary SLHCs subject to section 10(c)(9)(C) of HOLA as ''Legacy Unitary Savings and Loan Holding Companies'' (LUSLHCs). Additionally, the Board proposes to revise the definition for Legal Authority Code (LAC) 412 to be applicable to unitary SLHCs subject to section 10(c)(9)(C), rather than section 10(c)(6)(B), of the HOLA, as the revised citation is the proper authority for LUSLHCs. The Board also proposes to remove the LAC 410 from Appendix A of the FR Y–10, which would no longer be used in light of the proposed change to LAC 412.

FR Y–10 Legal Authority Code Descriptions

The Board proposes to revise the FR Y–10 instructions to update the description for legal authority codes 14, 68 and 999. The descriptions contain outdated terminology, and the revisions provide updated guidance from the relevant statutory language.

FR Y–10 Covered Savings Associations

The Board proposes to revise the Savings and Loan Holding Company schedule of the FR Y–10 form and instructions by adding as a reportable change in legal authority a notice by an HC's subsidiary federal savings association (FSA) to the Office of the Comptroller of the Currency (OCC) to operate as a CSA. Section 5A of HOLA permits FSAs that meet certain criteria to elect national bank powers and operate as CSAs without having to change their charters by submitting a notice of election to the OCC.[4] With limited exceptions, the Federal Reserve treats CSAs as national banks and their controlling HCs as bank holding companies. Eligible FSAs have been able to take this election since May 24, 2019, when the OCC issued its final rule on CSAs. CSAs and their controlling HCs are currently not required to provide the Federal Reserve notice of the election and there is currently no publicly available way to collect this information. Given that the CSA election materially changes the nature of supervision and regulation of the electing FSA and its controlling HC, this revision would allow the Federal Reserve to track this change in legal authority in a timely matter.

A new box with the company type labeled ''Federal Savings Association/ Covered Savings Association'' will also be added to item 9, Savings and Loan Type, for eligible reporters. Additionally, the Board proposes to update the Glossary to define CSAs.

FR Y–10 Description of Savings Association as Nonbank Company

The Board proposes to update the FR Y–10 forms and instructions to remove references to a savings association as a nonbanking company. This change would reduce confusion since a savings association company is not considered to be a nonbank company for FR Y–10 reporting purposes as the transactions involving these entities are reported in the Savings and Loan Schedule.

FR Y–10 Head Office Location

The Board proposes to revise the FR Y–10 instructions to clarify that a head office location of a depository institution may also include a separately licensed branch at the same address. This clarification will help to reduce confusion on when a head office location should be reported as a branch and how to accurately identify all bank branches. The Board also proposes to revise the FR Y–10 instructions to clarify that reporters should use the location where the main activities and operations of an entity are conducted when reporting the head office of an entity without a brick-and-mortar location.

FR Y–10 State of Incorporation

The Board proposes to revise the FR Y–10 instructions to require nationally chartered entities to indicate that they are ''federally chartered'' when reporting where they are incorporated. The current instructions require the state of incorporation to be reported for all reportable entities, but do not include instructions for how nationally chartered entities should report.

FR Y–6 and FR Y–10 Recordkeeping Requirement

Finally, the Board proposes to revise the FR Y–6 and the FR Y–10 instructions to require respondents to maintain in their files a physical copy of the manually signed FR Y–6 and FR Y–10 submissions. These reports do not currently account for recordkeeping, and this information must be maintained for a period of three years following submission.

Legal authorization and confidentiality: The FR Y–6 is authorized by the Board's reporting authorities, which are located in section 5(c)(1) of the BHC Act for BHCs (12 U.S.C. 1844(c)(1)), section 10(b)(2) of HOLA for SLHCs (12 U.S.C. 1467a(b)(2)), and section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) for securities holding companies (12 U.S.C. 1850a(c)(1)). The Board has authority to require IHCs to file the FR Y–6 pursuant to section 5(c) of the BHC Act (12 U.S.C. 1844(c)) and sections 102(a)(1) and 165 of the Dodd-Frank Act (12 U.S.C. 5311(a)(1) and 5365).[5] The Board has the authority to require any top-tier HC that is organized under foreign law but is not a FBO, and any FBO that does not meet the requirements of and is not treated as a qualifying FBO under Regulation K, to file the FR Y–6 under sections 8(a) and 13(a) of the International Banking Act of 1978 (IBA) (12 U.S.C. 3106(a) and 3108(a)) and section 5(c)(1) of the BHC Act (12 U.S.C. 1844(c)(1)). Section 8(a) of the IBA makes certain FBOs subject to the provisions of the BHC Act, and

[3] 85 FR 12398 (March 2, 2020).

[4] 12 U.S.C. 1464a.

[5] Section 102(a)(1) of the Dodd-Frank Act (12 U.S.C. 5311(a)(1)), defines ''bank holding company'' for purposes of Title I of the Dodd-Frank Act to include FBOs that are treated as bank holding companies under section 8(a) of the IBA (12 U.S.C. 3106(a)). The Board has required, pursuant to section 165(b)(1)(B)(iv) of the Dodd-Frank Act (12 U.S.C. 5365(b)(1)(B)(iv)), certain FBOs subject to section 165 of the Dodd-Frank Act to form U.S. IHCs. Accordingly, the parent foreign-based organization of a U.S. IHC is treated as a BHC for purposes of the BHC Act and section 165 of the Dodd-Frank Act. Because section 5(c) of the BHC Act authorizes the Board to require reports from subsidiaries of BHCs, section 5(c) provides authority to require U.S. IHCs to report the information contained in the FR Y–6.

section 13(a) of the IBA authorizes the Board to ''issue such rules, regulations, and orders as'' it may deem necessary in order to perform its ''respective duties and functions under this chapter and to administer and carry out the provisions and purposes of this chapter and prevent evasions thereof.''

The FR Y–7 is authorized by sections 8(a) and 13(a) of the IBA and section 5(c)(1) of the BHC Act.

The FR Y–10 and FR Y–10E are authorized by the Board's reporting authorities, which are located in section 5(c)(1) of the BHC Act for BHCs, section 10(b)(2) of HOLA for SLHCs, and section 618 of the Dodd-Frank Act for securities holding companies. The Board is authorized to require state member banks and agreement and Edge corporations to file the FR Y–10 by reporting authorities located in sections 9(6), 25, and 25A of the Federal Reserve Act (FRA) (for state member banks, agreement corporations, and Edge corporations, respectively) (12 U.S.C. 324, 602, and 625, respectively). Similarly, information collection from national banks under the FR Y–10 and FR Y–10E with respect to their foreign branches, their investments made under Subpart A of Regulation K, and foreign branches of their foreign subsidiaries that are investments made under Subpart A of Regulation K, is authorized by the reporting authorities located in sections 25 and 25A of the FRA. The Board has the authority to require FBOs to file the FR Y–10 under sections 8(a) and 13(a) of the IBA and section 5(c)(1) of the BHC Act.

Information collections under the FR Y–6, FR Y–7, and FR Y–10 are mandatory. Information collections under the FR Y–10E are voluntary.

Individual respondents may request that information submitted to the Board through the FR Y–6, FR Y–7, FR Y–10, and FR Y–10E be kept confidential. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on a case-by-case basis. To the extent a respondent submits nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, the respondent may request confidential treatment pursuant to exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)). To the extent a respondent submits personal, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of privacy, the respondent may request confidential treatment pursuant to exemption 6 of the FOIA (5 U.S.C. 552(b)(6)). Additionally, personal home addresses of securities holders submitted in response to the FR Y–7 will be treated as confidential pursuant to exemption 6 of the FOIA.

Board of Governors of the Federal Reserve System.

Dated: May 3, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–09850 Filed 5–6–22; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

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 paragraph 7 of the Act.

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 May 24, 2022.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org.*

1. *The Williams Family 2021 Irrevocable Trust Agreement and James L. Williams III, individually, and as trustee, both of Casselton, North Dakota;* to join the Williams Family Group, a group acting in concert, to retain voting shares of First Financial Corporation, and thereby indirectly retain voting shares of BankNorth, both of Arthur, North Dakota.

Board of Governors of the Federal Reserve System, May 4, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–09930 Filed 5–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment for the Ohio Patient Safety Institute

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ accepted a notification of proposed voluntary relinquishment from the Ohio Patient Safety Institute, PSO number P0041, of its status as a PSO, and has delisted the PSO accordingly.

DATES: The delisting was effective at 12:00 Midnight ET (2400) on April 30, 2022.

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, 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 Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3,

published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Ohio Patient Safety Institute to voluntarily relinquish its status as a PSO. Accordingly, the Ohio Patient Safety Institute, PSO number P0041, was delisted effective at 12:00 Midnight ET (2400) on April 30, 2022.

Ohio Patient Safety Institute has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov*.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–09843 Filed 5–6–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Membership To Serve on Initial Review Group for Scientific Peer Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for nominations for membership to serve on initial review group for scientific peer review.

SUMMARY: This is to invite the public to nominate members to the Agency for Healthcare Research and Quality (AHRQ) Initial Review Group (IRG) responsible for the scientific peer review of AHRQ grant applications. The AHRQ IRG conducts scientific and technical review for health services research grant applications and is comprised of five subcommittees or study sections, each with a particular research focus. AHRQ is seeking nominations for scientific reviewers in specific competency domains to evaluate grant applications.

DATES: Nominations should be received on or before June 1, 2022.

ADDRESSES: Nominations should be submitted by email to *dsr@ahrq.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Celeste Torio, Ph.D., MPH., AHRQ, (301) 427–1664 or by email at *celeste.torio@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: This is to invite the public to nominate members to the Agency for Healthcare Research and Quality (AHRQ) Initial Review Group (IRG) responsible for the scientific peer review of AHRQ grant applications. AHRQ is required to conduct appropriate scientific peer review of grant applications pursuant to *42 U.S.C. 299c–1.* The AHRQ IRG conducts scientific and technical review for health services research grant applications and is comprised of five subcommittees or study sections, each with a particular research focus. AHRQ is seeking nominations for scientific reviewers in specific competency domains to evaluate grant applications.

AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services (DHHS) and with other partners to make sure that the evidence is understood and used. AHRQ works to fulfill its mission by supporting health services research, evaluation, demonstration, dissemination, and training grants.

The peer review of AHRQ grant applications involves an assessment conducted by panels of qualified experts established according to scientific disciplines or medical specialty areas. Members of the IRG will be selected based upon their training and experience in relevant scientific and technical fields, taking in account, among other factors: (1) The level of formal education and pertinent expertise and experience; (2) extent of engagement in relevant research; (3) extent of professional recognition; (4) need for specialization in relevant field; and (5) appropriate representation based on gender, racial/ethnic origin, and geography. See *42 CFR 67.15(a)(2).*

The IRG is comprised of five subcommittees, or study sections, each with a particular emphasis around which peer reviewer expertise is assembled. AHRQ seeks nominations for each of the subcommittee competency domains described below:

Health Care Effectiveness and Outcomes Research: End-stage renal disease; cardiovascular disease; pediatrics; pharmacologist in opioid management; biostatisticians in health services research; health disparities and social determinants of health.

Healthcare Safety and Quality Improvement Research: Pharmacists with expertise in informatics; infectious diseases specialists; geriatricians; surgeons with a specialty in diagnostic error; health disparities and social determinants of health.

Healthcare Information Technology Research: Biomedical and consumer health informatics; family medicine; health care data analysis; health information technology; health services research in patient-oriented research; electronic health record and data for research; population-based studies in medicine; epidemiology; telehealth/telemedicine; emergency medicine; insurance benefit design; chronic condition care; natural language processing and machine learning; social networking and its determinants of health; health disparities and social determinants of health.

Healthcare Systems and Value Research: Health statistics; health care outcome research; evaluation and survey methods; health system and service research; health care policy research; health economics research; large database analysis; private health insurance/Medicaid and Medicare; learning laboratory development; health disparities and social determinants of health.

Health Care Research Training: Clinicians with knowledge of health policy; Medicare and Medicaid;

addiction medicine; health disparities and social determinants of health.

Additional study section descriptive information can be found here:

Study Section Rosters: http://www.ahrq.gov/funding/process/study-section/peerrev.

Study Section Descriptions: http://www.ahrq.gov/funding/process/study-section/peerdesc.

Study Section Research Foci: http://www.ahrq.gov/funding/process/study-section/resfoci.

Interested individuals may nominate themselves, and organizations and individuals may nominate one or more qualified persons for study section membership. A diversity of perspectives is valuable to AHRQ's work. To help obtain a diversity of perspectives among nominees, AHRQ encourages nominations of women and members of minority groups. AHRQ also seeks broad geographic representation. All nominations must be submitted electronically, and should include:

1. A copy of the nominee's current curriculum vitae and contact information, including mailing address, phone number, and email address.

2. Preferred study section assignment.

Dated: May 3, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–09834 Filed 5–6–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0728]

Celgene Corporation and Teva Pharmaceutical Industries Ltd.; Withdrawal of Approval of Peripheral T-Cell Lymphoma Indication for ISTODAX (Romidepsin) for Injection and Romidepsin Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the peripheral T-cell lymphoma (PTCL) indication for ISTODAX (romidepsin) for injection, approved under new drug application (NDA) 022393, held by Celgene Corporation, 86 Morris Ave., Summit, NJ 07901 (Celgene). We are also announcing the withdrawal of approval of the same indication for Romidepsin injection, approved under NDA 208574, held by Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054 (Teva). Celgene and Teva have voluntarily requested that FDA withdraw approval of this indication and have waived their opportunity for a hearing.

DATES: Approval was withdrawn as of May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 16, 2011, FDA approved an additional indication for Celgene's new drug application (NDA) 22393 for ISTODAX (romidepsin) for injection, 10 mg, specifically for treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of Celgene's ISTODAX (romidepsin) for injection for PTCL included a required postmarketing clinical trial intended to verify the clinical benefit of romidepsin (the Ro-CHOP study) for PTCL.

On March 13, 2020, FDA approved Teva's NDA 208574 for Romidepsin injection, 10 mg/2 milliliter, for treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of Teva's Romidepsin injection for PTCL also included a required postmarketing clinical trial intended to verify the clinical benefit of romidepsin for PTCL. Teva's Romidepsin injection product was approved under the 505(b)(2) approval pathway, and the listed drug relied upon is Celgene's NDA 22393, ISTODAX (romidepsin) for injection.

On August 6, 2020, Celgene submitted high level results from the Ro-CHOP study to FDA, which indicated the study failed to meet its primary endpoint of progression free survival. On May 14, 2021, Celgene informed FDA that after careful consideration, Celgene decided to voluntarily withdraw the PTCL indication from ISTODAX (romidepsin) for injection.

On June 17, 2021, Celgene submitted a supplemental NDA proposing to remove the PTCL indication. On July 14, 2021, Celgene submitted a letter asking FDA to withdraw approval of the PTCL indication pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing.

On August 27, 2021, Teva submitted a labeling supplement proposing to remove the PTCL indication. On September 12, 2021, the Agency requested Teva voluntarily request withdraw of the PTCL indication pursuant to § 314.150(d) and waive its opportunity for a hearing. On September 14, 2021, Teva amended its supplement by submitting a cover letter requesting withdrawal of approval of the PTCL indication pursuant to § 314.150(d) and waiving its opportunity for a hearing.

Therefore, under § 314.150(d), approval of the PTCL indications for ISTODAX (romidepsin) for injection, and Romidepsin injection, is withdrawn effective May 9, 2022. Withdrawal of approval of the PTCL indication does not affect any other approved indication(s) for ISTODAX (romidepsin) for injection or Romidepsin injection.

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09889 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with warning plans for smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by July 8, 2022.

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 July 8, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 8, 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 No. FDA–2013–N–0190 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Smokeless Tobacco Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Warning Plans for Smokeless Tobacco Products

OMB Control Number 0910–0671—Extension

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402) requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section (b)(3)(A) of 15 U.S.C. 4402 requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA.

To implement these statutory requirements, warning plans are reviewed by FDA, upon submission by respondents. FDA published a draft guidance entitled ''Submission of

Warning Plans for Cigarettes and Smokeless Tobacco Products'' on September 9, 2011, which describes the information and format to be submitted for smokeless plans (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-warning-plans-cigarettes-and-smokeless-tobacco-products*). Submitters may also visit a web page that describes the smokeless tobacco labeling and warning statement requirements (*https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements*). Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan. Warning plans can be submitted either electronically or in paper format. The Center for Tobacco Products (CTP) Portal, available at *https://ctpportal.fda.gov/ctpportal/login.jsp,* provides a secure online system for electronically submitting documents and receiving messages from CTP.

Based on our experience with the information collection over the past 3 years, we retain our estimate of 60 hours to complete an initial rotational plan. We estimate half this time for preparing and submitting a supplement to an approved plan (30 hours).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of initial rotational plans for health warning statements	1	1	1	60	60
Supplement to approved plan	4	1	4	30	120
Total					180

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates a total of 1 respondent will submit a new original warning plan yearly and take 60 hours to complete a rotational warning plan for a total of 60 burden hours. In addition, FDA estimates a total of 4 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 120 hours. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. Therefore, we have decreased our estimate burden by 360 hours.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09885 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit and to Applied DNA Sciences, Inc., for the Linea COVID–19 Assay Kit. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit is revoked as of April 15, 2022. The Authorization for the Linea COVID–19 Assay Kit is revoked as of April 20, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 11, 2021, FDA issued an EUA to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On May 13, 2020, FDA issued an EUA to Applied DNA Sciences, Inc. for the Linea COVID–19 Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria

under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

In a request received by FDA on March 17, 2022, Bio-Rad Laboratories, Inc., requested revocation of, and on April 15, 2022, FDA revoked, the Authorization for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit. Because Bio-Rad Laboratories, Inc. notified FDA that it has ceased U.S. distribution of the Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on April 7, 2022, Applied DNA Sciences, Inc., requested revocation of, and on April 20, 2022, FDA revoked, the Authorization for the Linea COVID–19 Assay Kit. Because Applied DNA Sciences, Inc. notified FDA that it has decided to discontinue distribution of the Linea COVID–19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID–19 Assay Kit, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/*.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, and Applied DNA Sciences, Inc., for the Linea COVID–19 Assay Kit. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

April 14, 2022

Elizabeth Platt EdD, MS, MBA
Sr. Director, Regulatory & Clinical Affairs | Americas
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 92647
Re: Revocation of EUA202965

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., received via email on March 17, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA, with an effective date of April 15, 2022, for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit issued on February 11, 2021, and amended on September 23, 2021. Bio-Rad Laboratories, Inc. ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit on March 2, 2022, and has discontinued this assay.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Bio-Rad Laboratories, Inc. has notified FDA that it has ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, per your request, effective April 15, 2022, FDA hereby revokes EUA202965 for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. Effective as of April 15, 2022, the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 20, 2022

Clay D. Shorrock, Esq.
Chief Legal Officer and Exec. Dir., Business Development
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790
Re: Revocation of EUA200474

Dear Mr. Shorrock:

This letter is in response to the request from Applied DNA Sciences, Inc., received on April 7, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Linea COVID-19 Assay Kit issued on May 13, 2020, re-issued on May 11, 2021, and amended on July 8, 2020, July 30, 2020, September 25, 2020, November 21, 2020, July 21, 2021, and September 23, 2021. Applied DNA Sciences, Inc. indicated that it is no longer distributing or utilizing the Linea COVID-19 Assay Kit. Applied DNA Sciences, Inc. has transitioned to the use of the Linea 2.0 COVID-19 Assay and other EUA-authorized tests.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Applied DNA Sciences, Inc. has notified FDA that it has decided to discontinue distribution of the Linea COVID-19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID-19 Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200474 for the Linea COVID-19 Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Linea COVID-19 Assay Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: James A. Hayward, Ph.D., Chairman, President & CEO, Applied DNA Sciences, Inc.

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09887 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1112]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 8, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitary Program

OMB Control Number 0910–0021—Extension

Under section 243 of the Public Health Service Act (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the U.S. molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitors its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish dealers to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate'' (available at *https://www.fda.gov/media/72094/download*). FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List (ICSSL),'' a monthly comprehensive listing of all molluscan shellfish dealers certified under the cooperative program (available at *https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list*). If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and prevent the distribution in the United States of shellfish processed by uncertified dealers. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the ICSSL, the effectiveness of the NSSP would be nullified. The ICSSL is also used to identify U.S. shellfish dealers eligible to obtain health certificates and export to certain countries or regions.

FDA has been collecting information to construct the ICSSL since 2001. FDA is seeking to add one new data field to Form FDA 3038, the ''FDA Establishment Identifier'' (FEI number). The FEI number is a unique number assigned by FDA to identify FDA-regulated facilities. FDA will explore whether the FEI can be used to retrieve data on shellfish dealers from existing FDA systems, which could reduce the number of required data elements that firms have to submit on Form FDA 3038.

The information collection also includes providing certain documents demonstrating compliance with the NSSP. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for molluscan shellfish are equivalent to their system of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. FDA uses this information to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter is in compliance with the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission's (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union's (EU) system of controls, the EC is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities with firms seeking to export raw molluscan shellfish to the EU. This documentation includes, but is not limited to:

- A list of growing areas with an Approved classification;
- the most recent sanitary survey for each growing area with an Approved classification; and
- the most recent inspection report for each firm seeking to export shellfish to the EU.

Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We plan to provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Description of Respondents: Respondents to this collection are participating State and local regulatory agencies and foreign nations.

In the **Federal Register** of November 4, 2022 (86 FR 60840), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate.	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of Other Records Related to Participation in the NSSP.	N/A	13	1	13	0.25 (15 minutes)	3.25
Total	.....	.....	.....	.....	.....	231.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

Dated: May 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09888 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9⅜%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2022. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2022–09840 Filed 5–6–22; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0166]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 8, 2022.

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: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0937–0166 and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: 42 CFR Subpart B: Sterilization of Persons in Federally Assisted Family Planning Projects.

Type of Collection: Reinstatement without change.

OMB No. 0937–0166

Abstract: The Office of Population Affairs (OPA), Office of the Assistant Secretary for Health, requests a reinstatement without change of a currently approved collection for the disclosure and recordkeeping requirements codified at 42 CFR part 50, subpart B (''Sterilization of Persons in Federally Assisted Family Planning Projects''). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the PHS. It provides additional procedural protection to the individual and the regulation requires that the consent form be a copy of the form that is appended to the PHS regulation. In 2003, the PHS sterilization consent form was revised to conform to OMB government-wide standards for the

collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. OPA is requesting a three-year clearance.

Estimated Annualized Burden Table:

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Information Disclosure for Sterilization Consent. Form	Citizens Seeking Sterilization	100,000	1	1	100,000
Record-keeping for Sterilization Consent Form.	Citizens Seeking Sterilization	100,000	1	15/60	25,000
Total					125,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–09848 Filed 5–6–22; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel; Review of Clinical Study Applications.

Date: June 22, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite #670, Bethesda, MD 20892, (301) 827–4639, *yun.mei@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 4, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09883 Filed 5–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Initial Review Group; Mental Health Services Study Section.

Date: June 7–8, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Room 6136, MSC 9606, Bethesda, MD 20852, 301–443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 4, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09884 Filed 5–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; HEAL Initiative: K12.

Date: June 6, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Abhignya Subedi, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *abhi.subedi@nih.gov.*

Name of Committee: Neurological Sciences Training Initial Review Group; NST–2 Study Section NINDS Post-doc Fellowships.

Date: June 8–10, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Deanna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *deanna.adkins@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; BRAIN Initiative: Research Resource Grants for Technology Integration and Dissemination (U24 Clinical Trial Not Allowed).

Date: June 9, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Bo-Shiun Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *bo-shiun.chen@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Blueprint Neurotherapeutics Network Small Molecule Drug Discovery for Neurological Disorders.

Date: June 10, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *joel.saydoff@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; DSPAN F99 Application Review.

Date: June 13–14, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Lataisia Cherie Jones, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–9223, *lataisia.jones@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 3, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09863 Filed 5–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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: National Institute on Drug Abuse Special Emphasis Panel; Accelerating the Pace of Drug Abuse Research Using Existing Data.

Date: June 7–8, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebekah Feng, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–7245, *rebekah.feng@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Pharmacokinetics (PK) and Pharmacodynamics (PD) of THC in Cannabis and Cannabis Products.

Date: June 8, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Preethy Nayar, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, Bethesda, MD 20892, 301–443–4577, *nayarp2@csr.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: Understanding Polysubstance Use and Improving Service Delivery to Address Polysubstance Use.

Date: June 22, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sheila Pirooznia, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 496–9350, *sheila.pirooznia@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Elucidating the Effects of ART on Neuronal Function in the Context of SUD and HIV.

Date: June 22, 2022.

Time: 12:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5819, *gm145a@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Advancing Validated Drug Targets for Substance Use Disorders.

Date: June 28, 2022.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 3, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09864 Filed 5–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2022 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Intent to award supplemental funding to the Prevention Technology Transfer Centers (PTTC) National Coordinating Center (NCC) Funding Opportunity Announcement SP–19–001 grant recipient funded in FY 2018.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement (in scope of the parent award) up to $450,000 (total funding) for one-year to the PTTC–NCC recipient. This recipient was funded in FY 2018 under the Prevention Technology Transfer Centers (PTTC) Cooperative Agreements Funding Opportunity SP–19–001 with a project end date of April 30, 2023. The PTTC–NCC will develop a training curriculum for preventionists based on the Prevention Core Competencies to address the workforce needs of entry-level and mid-level preventionists. This training curriculum will build upon and complement existing workforce training curricula and resources (*e.g.,* Substance Abuse Prevention Specialist Training, IC&RC guidebook).

The required activities for this supplement are as follows:

1. Collaborate with interested stakeholders (*e.g.,* National Association of State Alcohol and Drug Abuse Directors, Community Anti-Drug Coalitions of America, Society for Prevention Research) to develop the curriculum outline and training curriculum for entry-level and mid-level preventionists as well as serve as field reviewers and pilot test sites.

2. Develop an evaluation plan to assess the effectiveness of the training curriculum once it is deployed in the field. Training delivery must be available in virtual and in-person environments.

3. Develop a training of trainers (ToT) curricula, as appropriate, and identify supplemental TA services to be provided as follow-up. The NCC will develop a strategy to deploy this training with the aim of training 5,000 entry-level and mid-level preventionists by the end of FY 2023.

4. In coordination with SAMHSA Regional Offices and the National Prevention Network Coordinators, strategize regional deliveries of the prevention curriculum to complement existing state workforce development programming.

5. Develop a roll-out plan to promote the availability of the curriculum and training opportunities (*e.g.,* social media and other communications resources for use by regional partners) and reduce barriers to training access. Conduct ''real world'' testing of the curriculum with diverse populations.

This is not a formal request for application. Assistance will only be provided to the one eligible PTTC–NCC based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Funding Opportunity Title: FY 2018 Prevention Technology Transfer Centers (PTTC) Cooperative Agreements Funding Opportunity SP–19–001.

Assistance Listing Number: 93.243.

Authority: Section 509 (42 U.S.C. 290bb–4) of the Public Health Service Act, as amended.

Justification: Eligibility for this supplemental funding is limited to the PTTC–NCC grant recipient funded in FY 2018 from the PTTC Cooperative Agreements funding opportunity SP–19–001. This organization has the overarching coordinating responsibilities and is uniquely capable of developing training resources that aide the 10 regional PTTCs, the PTTC Hispanic and Latino and the PTTC Tribal Affairs Centers in their work with constituents and grantees under their purview. Specifically, the PTTC–NCC is uniquely capable of developing a training curriculum for preventionists based on the Prevention Core Competencies.

FOR FURTHER INFORMATION CONTACT: Thia Walker, DrPH, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–1835; email: *thia.walker@samhsa.hhs.gov.*

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–09867 Filed 5–6–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2022 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Intent to award supplemental funding to the Prevention Technology Transfer Centers (PTTC) Regional Centers, the PTTC Hispanic and Latino Center, and the PTTC Tribal Affairs Center grant recipients funded in FY 2018 from Funding Opportunity Announcement SP–19–001.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting administrative supplements (in scope of the parent award) up to $150,000 each for one-year to the ten PTTC Regional Centers, the PTTC Hispanic and Latino Center and the PTTC Tribal Affairs Center for a total funding amount of $1,800,000. These grant recipients were funded in FY 2018 under the PTTC Cooperative Agreements, funding announcement SP–19–001 and have a project end date of April 30, 2023. The supplemental funds will be used to: (1) Develop a Prevention Fellowship Program (PFP); (2) develop and sustain a well-trained and knowledgeable cadre of prevention professionals who understand and exemplify the principles and best practices of substance abuse prevention; and (3) prepare fellows to achieve certification from the International Certification and Reciprocity Consortium (IC&RC) Certified Prevention Specialist (CPS) exam. The PFP shall support internships for fellows in the following areas: Hands-on experience working in state agencies while supported by state agency mentors; virtual and in-person training in professional development and prevention; acquiring proficiency in appropriate core competencies in preparation for the CPS exam; developing management and leadership skills; and preparing for potential employment opportunities within the prevention field. This is not a formal request for application. Assistance will only be provided to the twelve eligible PTTC Centers based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Funding Opportunity Title: FY 2018 Prevention Technology Transfer Centers (PTTC) Cooperative Agreements Funding Opportunity SP–19–001.

Assistance Listing Number: 93.243.

Authority: Section 509 (42 U.S.C. 290bb–4) of the Public Health Service Act, as amended.

Justification: Eligibility for this supplemental funding is limited to the twelve PTTC Centers funded in FY 2018 under the PTTC Cooperative Agreements as they are uniquely positioned to engage in the regionally-

focused prevention activity being funded through this supplement.

FOR FURTHER INFORMATION CONTACT: Thia Walker, DrPH., Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–1835; email: *thia.walker@samhsa.hhs.gov.*

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–09866 Filed 5–6–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2022–0003]

Notice of President's National Security Telecommunications Advisory Committee Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of *Federal Advisory Committee Act* (FACA) meeting; request for comments.

SUMMARY: CISA is publishing this notice to announce the following President's National Security Telecommunications Advisory Committee (NSTAC) meeting. This meeting will be partially closed to the public.

DATES:

Meeting Registration: Registration to attend the meeting is required and must be received no later than 5:00 p.m. Eastern Time (ET) on May 17, 2022. For more information on how to participate, please contact *NSTAC@cisa.dhs.gov.*

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5:00 p.m. ET on May 17, 2022.

Written Comments: Written comments must be received no later than 5:00 p.m. ET on May 17, 2022.

Meeting Date: The NSTAC will meet on May 24, 2022, from 9:00 a.m. to 3:30 p.m. ET. The meeting may close early if the committee has completed its business.

ADDRESSES: The May 2022 NSTAC Meeting's open session is set to be held in person at 1717 H Street NW, Washington, DC. For information on services for individuals with disabilities, or to request special assistance, please email *NSTAC@cisa.dhs.gov* by 5:00 p.m. ET on May 17, 2022.

Comments: Members of the public are invited to provide comment on issues that will be considered by the committee as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials that may be discussed during the meeting will be made available for review at *https://www.cisa.gov/nstac* on May 9, 2022. Comments should be submitted by 5:00 p.m. ET on May 17, 2022 and must be identified by Docket Number CISA–2022–0003. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Please follow the instructions for submitting written comments.
- *Email: NSTAC@cisa.dhs.gov.* Include the Docket Number CISA–2022–0003 in the subject line of the email.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the Docket Number for this action. Comments received will be posted without alteration to *www.regulations.gov,* including any personal information provided. You may wish to review the Privacy & Security Notice which is available via a link on the homepage of *www.regulations.gov.*

Docket: For access to the docket and comments received by the NSTAC, please go to *www.regulations.gov* and enter docket number CISA–2022–0003.

A public comment period is scheduled to be held during the meeting from 2:25 p.m. to 2:35 p.m. ET. Speakers who wish to participate in the public comment period must email *NSTAC@cisa.dhs.gov* to register. Speakers should limit their comments to 3 minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT: Christina Berger, 202–701–6354, *NSTAC@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The NSTAC is established under the authority of Executive Order (E.O.) 12382, dated September 13, 1982, as amended by E.O. 13286, continued and amended under the authority of E.O. 14048, dated September 30, 2021. Notice of this meeting is given under FACA, 5 U.S.C. Appendix (Pub. L. 92–463). The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications and cybersecurity policy.

Agenda: The NSTAC will meet in an open session on Tuesday, May 24, 2022, to discuss current NSTAC activities and the Government's ongoing cybersecurity and NS/EP communications initiatives. This open session will include: (1) A keynote address; (2) a deliberation and vote on the *NSTAC Report to the President on Enhancing U.S. Leadership in International Communications Technology Standards;* and (3) a status update from the NSTAC Information Technology and Operational Technology Convergence Subcommittee.

The committee will also meet in a closed session from 9:00 a.m. to 12:00 p.m. during which time: (1) Senior Government intelligence officials will provide a threat briefing concerning threats to NS/EP communications and engage NSTAC members in follow-on discussion; and (2) NSTAC members and senior Government officials will discuss potential NSTAC study topics.

Basis for Closure: In accordance with section 10(d) of FACA and 5 U.S.C. 552b(c)(1), *The Government in the Sunshine Act,* it has been determined that a portion of the agenda requires closure, as the disclosure of the information that will be discussed would not be in the public interest.

These agenda items are the: (1) Classified threat briefing and discussion, which will provide NSTAC members the opportunity to discuss information concerning threats to NS/EP communications with senior Government intelligence officials; and (2) potential NSTAC study topics discussion. The briefing is anticipated to be classified at the top secret/sensitive compartmented information level. Disclosure of these threats during the briefing, as well as vulnerabilities and mitigation techniques, is a risk to the Nation's cybersecurity posture since adversaries could use this information to compromise commercial and Government networks. Subjects discussed during the potential study topics discussion are tentative and are under further consideration by the committee.

Therefore, this portion of the meeting is required to be closed pursuant to section 10(d) of FACA and 5 U.S.C. 552b(c)(1).

Dated: May 3, 2022.

Christina Berger,

Designated Federal Officer, NSTAC Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2022–09915 Filed 5–6–22; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–17]

Proposed Information Collection: Unsheltered and Rural Homelessness Special NOFO Competition, OMB Control No.: 2506–0218

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 16, 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: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

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: Brett Esders, Senior SNAPS Specialist, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; Email: *Brett.D.Esders@hud.gov.*

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Unsheltered and Rural Homelessness Special NOFO Competition.

OMB Approval Number: 2506–0218.

Type of Request: New.

Form Number: SF–424, HUD–2991, HUD–2993, HUD–2880, SF–LLL, HUD–50070 HUD 40090–4.

Description of the need for the information and proposed use: Section 231 of the Department of Housing and Urban Development Appropriations Act, 2020 (42 U.S.C. 11364a; Pub. L. 116–94, approved December 20, 2019) provided HUD with authority to use recaptured CoC Program funds for four purposes, two of which area: (1) Grants under the Continuum of Care program under Subtitle C of title IV of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11381 *et seq.*); and (2) Not less than 10 percent of the amounts shall be used only for grants in rural areas under the Continuum of Care program, to include activities eligible under the Rural Housing Stability Assistance program under section 491 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11408) that are not otherwise eligible under the Continuum of Care program. HUD is providing funding for Continuums of Care (CoCs) using these authorities to help them address unsheltered homelessness and, in rural areas, to implement the unique strategies often needed to reduce homelessness and to add resources and infrastructure that is lacking. Without asking for this information, HUD will be unable to ensure the communities awarded have the capacity to implement projects that support an overall strategy, based in data and evidence, to reduce unsheltered homelessness and amongst those individuals who are most vulnerable.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CoC Applications:							
CoC Application	250	1	250	15	3,750	$41.37	$155,137.50
CoC Priority Listing and Reallocation Forms	250	1	250	5	1,250	41.37	51,712.50
HUD–2991	250	1	250	3	750	41.37	31,027.50
Subtotal CoC Application ..	250	1	250	23	5,750	41.37	237,877.50
Project Applications:							
New Project	1,500	1	1,500	1.50	2,250	41.37	93,082.50
CoC Planning	250	1	250	1.50	375	41.37	15,513.75
UFA Costs	12	1	12	1	12	41.37	496.44
SF–424	1,500	1	1,500	0.05	75	41.37	3,102.75
HUD–2880	1,500	1	1,500	0.05	75	41.37	3,102.75
HUD–50070	1,500	1	1,500	0.05	75	41.37	3,102.75
SF LLL	1,500	1	1,500	0.05	75	41.37	3,102.75
Certification of Lobbying	1,500	1	1,500	0.05	75	41.37	3,102.75
HUD–40090–4	1,500	1	1,500	0.05	75	41.37	3,102.75
Subtotal Project Applications Submissions	1,762	1	1,762	4.3	3,087	41.37	127,709.19
CoC and Project Applications Overall Total:							
Total for CoC and Project Applications	2,012	1	2,012	25.3	8,337	41.37	365,586.69

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) If the information will be processed and used in a timely manner;

(3) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(4) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(5) 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.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2022–09933 Filed 5–6–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2022–N024; FXES11130300000–223–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before June 8, 2022.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX; see table in **SUPPLEMENTARY INFORMATION**):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective application number (*e.g.,* Application No. TEXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Nathan Rathbun, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Nathan Rathbun, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications:

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
PER0038946 ..	Red Cliff Band of Lake Superior Chippewa, Bayfield, WI.	Gray wolf (*Canis lupus*).	WI	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, radio collar, PIT tag, collect DNA samples, administer drugs, and release.	New.
PER0038948 ..	USDA Forest Service, Amherst, MA.	Rusty patched bumble bee (*Bombus affinis*).	MN, WI	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, handle, and release.	New.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
PER0039248 ..	Jacob Powell, Sheridan, WY.	Rusty patched bumble bee (*Bombus affinis*), Poweshiek skipperling (*Oarisma poweshiek*), and Dakota skipper (*Hesperia dacotae*).	IA, IL, IN, MA, ME, MI, MN, ND, OH, SD, VA, WI, WV.	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, handle, and release.	New.
PER0039249 ..	Meredith Hoggatt, Pittsboro, IN.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and gray bat (*Myotis grisescens*).	AL, AR, CT, DC, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, TX, VI, VT, WI, WV, WY.	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture by mistnet and harp traps, handle, radio-tag, collect DNA samples, band, and release.	New.
PER0039255 ..	Ryan Schwegman, College Corner, OH.	Thirteen freshwater mussel species.	AR, DE, IA, IL, IN, KS, KY, MD, MI, MN, MO, NY, OH, OK, PA, TN, TX, VA, WI, WV.	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, handle, mark, relocate, collect for propagation purposes, and release.	New.
TE26953C	Karen Goodell, Newark, OH.	Rusty patched bumble bee (*Bombus affinis*).	Add: new locations — PA, MD, VA, WV — to existing authorized location: OH.	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, handle, and release.	Amend.
PER0039690 ..	Amy Toth, Ames, IA.	Rusty patched bumble bee (*Bombus affinis*).	IA, IL	Conduct presence/absence surveys, conduct studies to document habitat use, conduct population monitoring, and evaluate potential impacts.	Capture, handle, mark, release, DNA sample, pollen sample.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2022–09875 Filed 5–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R3–ES–2022–0040; FXES11140300000–223]

Draft Environmental Assessment and Proposed Habitat Conservation Plan; Receipt of an Application for an Incidental Take Permit, Jordan Creek Wind Energy Center, Warren and Benton Counties, Indiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from Jordan Creek Wind LLC (applicant), a subsidiary of NextEra Energy Resources LLC, for an incidental take permit (ITP) under the Endangered Species Act, for its Jordan Creek Wind Energy Center (project). If approved, the ITP would be for a 30-year period and

would authorize the incidental take of an endangered species, the Indiana bat, and a threatened species, the northern long-eared bat. The applicant has prepared a habitat conservation plan that describes the actions and measures that the applicant would implement to avoid, minimize, and mitigate incidental take of the Indiana bat and northern long-eared bat. We also announce the availability of a draft environmental assessment, which has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act. We request public comment on the application and associated documents.

DATES: We will accept comments received or postmarked on or before June 8, 2022.

ADDRESSES:

Document availability: Electronic copies of the documents this notice announces, along with public comments received, will be available online in Docket No. FWS–R3–ES–2022–0040 at *https://www.regulations.gov*.

Comment submission: Please specify whether your comment addresses the proposed HCP, draft EA, or both. You may submit written comments by one of the following methods:

- *Online: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R3–ES–2022–0040.
- *By hard copy:* Submit comments by U.S. mail to Public Comments Processing, Attn: Docket No. FWS–R3–ES–2022–0040; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: PRB/3W; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Scott Pruitt, Field Supervisor, Indiana Ecological Services Field Office by email at *scott_pruitt@fws.gov,* or telephone at 812–334–4261, extension 214; or Andrew Horton, Regional HCP Coordinator, Interior Region 3, by email at *andrew_horton@fws.gov* or telephone at 612–713–5337.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and its implementing regulations prohibit the ''take'' of animal species listed as endangered or threatened. Take is defined under the ESA as to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect [listed animal species], or to attempt to engage in such conduct'' (16 U.S.C. 1538). However, under section 10(a) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species, respectively, are found in the Code of Federal Regulations at 50 CFR 17.22 and 50 CFR 17.32.

Applicant's Proposed Project

The applicant requests a 30-year ITP to take the federally endangered Indiana bat (*Myotis sodalis*) and threatened northern long-eared bat (*Myotis septentrionalis*). The applicant determined that take is reasonably certain to occur incidental to operation of 146 wind turbines that have a total generating capacity of 404 megawatts and cover approximately 70,904 acres of private land. The proposed conservation strategy in the applicant's proposed HCP is designed to avoid, minimize, and mitigate the impacts of the covered activity on the covered species. The biological goals and objectives are to minimize potential take of Indiana bats and northern long-eared bats through on-site minimization measures and to provide habitat conservation measures for Indiana bats and northern long-eared bats to offset any impacts from operations of the project. The HCP provides on-site avoidance and minimization measures, which include turbine operational adjustments. The authorized level of take from the project is 193 Indiana bats and 97 northern long-eared bats over the 30-year project duration. To offset the impacts of the taking of Indiana bats and northern long-eared bats, the applicant proposes to protect known maternity colony habitat and staging/swarming habitat.

National Environmental Policy Act

The issuance of an ITP is a Federal action that triggers the need for compliance with NEPA. We prepared a draft EA that analyzes the environmental impacts on the human environment resulting from three alternatives: A no-action alternative, the proposed action, and a more restrictive alternative consisting of feathering at a rate of wind speed that results in less impacts to bats.

Next Steps

The Service will evaluate the permit application and the comments received to determine whether the application meets the requirements of section 10(a) of the ESA. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(l)(B) of the ESA have been met. If met, the Service will issue the requested ITP to the applicant.

Request for Public Comments

The Service invites comments and suggestions from all interested parties during a 30-day public comment period (see **DATES**). In particular, information and comments regarding the following topics are requested:

1. The environmental effects that implementation of any alternative could have on the human environment;

2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed;

3. Any threats to the Indiana bat and the northern long-eared bat that may influence their populations over the life of the ITP that are not addressed in the proposed HCP or EA; and

4. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Availability of Public Comments

You may submit comments by one of the methods shown under **ADDRESSES**. We will post on *https://regulations.gov* all public comments and information received electronically or via hardcopy. All comments received, including names and addresses, will become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and the NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR part 46).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2022–09837 Filed 5–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R3–ES–2022–0003; FXES11140300000–223]

Draft Environmental Assessment and Proposed Habitat Conservation Plan Amendment; Receipt of an Application for an Incidental Take Permit Amendment, Fowler Ridge Wind Farm, Benton County, Indiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments and information.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from Fowler Ridge Wind Farm LLC, Fowler Ridge II Wind Farm LLC, Fowler Ridge III Wind Farm LLC, and Fowler Ridge IV Wind Farm LLC, collectively referred to as Fowler Ridge (applicant), to amend an existing incidental take permit (ITP) under the Endangered Species Act, for its Fowler Ridge Wind Farm (project). If approved, the ITP would be extended for an additional 10-year period and would add authorization of incidental take of a threatened species, the northern long-eared bat, to the currently existing authorization to incidentally take the endangered Indiana bat. The applicant has prepared a proposed habitat conservation plan amendment that describes the actions and measures that the applicant would implement to avoid, minimize, and mitigate incidental take of the Indiana bat and northern long-eared bat. We also announce the availability of a draft environmental assessment, which has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act. We request public comment on the application and associated documents.

DATES: We will accept comments received or postmarked on or before June 8, 2022.

ADDRESSES:

Document availability: Electronic copies of the documents this notice announces, along with public comments received, will be available online in Docket No. FWS–R3–ES–2022–0003 at *http://www.regulations.gov.*

Comment submission: In your comment, please specify whether your comment addresses the proposed HCP, draft EA, or any combination of the aforementioned documents, or other supporting documents. You may submit written comments by one of the following methods:

- *Online: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R3–ES–2022–0003.
- *By hard copy:* Submit comments by U.S. mail to Public Comments Processing, Attn: Docket No. FWS–R3–ES–2022–0003; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: PRB/3W; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Scott Pruitt, Field Supervisor, Indiana Ecological Services Field Office, by email at *scott_pruitt@fws.gov,* or by telephone at 812–334–4261, extension 214; or Andrew Horton, Regional HCP Coordinator, Interior Region 3, by email at *andrew_horton@fws.gov,* or by telephone at 612–713–5337.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and its implementing regulations prohibit the ''take'' of animal species listed as endangered or threatened. ''Take'' is defined under the ESA as to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect [listed animal species], or to attempt to engage in such conduct'' (16 U.S.C. 1538). However, under section 10(a) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species, respectively, are found in the Code of Federal Regulations (CFR) at 50 CFR 17.22 and 50 CFR 17.32.

Applicant's Proposed Project

The applicant requests to amend their current 21-year ITP (TE95012A–0). The proposed HCP amendment, if approved, would extend the current permit term by 10 years. Because of the time already elapsed since the original issuance of the ITP, this extension would result in an amended ITP with a total 23-year permit term (2022–2044). In addition, the HCP amendment would add authorization to incidentally take the federally threatened northern long-eared bat (*Myotis septentrionalis*) to the ITP, and would in effect increase the allowable take of the federally endangered Indiana bat (*Myotis sodalis*), due to the permit term extension. The applicant determined that take is reasonably certain to occur incidental to operation of the 420 wind turbines at the project. The proposed conservation strategy in the applicant's proposed HCP amendment is designed to avoid, minimize, and mitigate the impacts of the covered activity on the covered species. The biological goals and objectives are to minimize potential take of Indiana bats and northern long-eared bats through on-site minimization measures and to provide habitat conservation measures for Indiana bats and northern long-eared bats to offset any impacts from operations of the project. The HCP amendment provides on-site avoidance and minimization measures, which include turbine operational adjustments. The estimated level of take from the project is 120 northern long-eared bats over the 24-year project duration and an additional 151 Indiana bats (above the 184 Indiana bats already authorized in the original ITP) due to the 10-year extension. To offset the impacts of the taking of Indiana bats and northern long-eared bats, the applicant proposes to protect known maternity colony habitat.

National Environmental Policy Act

The issuance of an ITP amendment is a Federal action that triggers the need for compliance with NEPA. We prepared a draft EA that analyzes the environmental impacts on the human environment resulting from three alternatives: A no-action alternative, the applicants' proposed alternative, and an alternative that provides coverage of only the northern long-eared bat.

Next Steps

The Service will evaluate the permit amendment application and the comments received to determine whether the application meets the requirements of section 10(a) of the ESA. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(l)(B) of the ESA have been met. If met, the Service will issue the requested ITP to the applicant.

Request for Public Comments

The Service invites comments and suggestions from all interested parties during a 30-day public comment period (see **DATES**). In particular, information and comments regarding the following topics are requested:

1. The effects that implementation of any alternative could have on the human environment;

2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed;

3. Any threats to the Indiana bat and the northern long-eared bat that may influence their populations over the life of the ITP that are not addressed in the proposed HCP or EA; and

4. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Availability of Public Comments

You may submit comments by one of the methods shown under **ADDRESSES**. We will post on *https://regulations.gov* all public comments and information received electronically or via hardcopy. All comments received, including names and addresses, will become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and the NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR part 46).

Sean Marsan,

Acting Assistant Regional Director, Ecological Services.

[FR Doc. 2022–09836 Filed 5–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–BSD–CONC–NPS0033333; PPWOBSADC0, PPMVSCS1Y.Y00000 (222); OMB Control Number 1024–0029]

Agency Information Collection Activities; National Park Service Concessions

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before July 8, 2022.

ADDRESSES: Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive, (MS—242) Reston, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number ''1024–0029'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR by mail, contact Kurt Rausch, Contract Management Team Lead, National Park Service, 1849 C Street NW, Washington, DC 20240; or by email at *kurt_rausch@nps.gov.* Please reference OMB Control Number 1024–0029 in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments 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 can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Private businesses under contract to the National Park Service manage food, lodging, tours, whitewater rafting, boating, and many other recreational activities and amenities in more than 100 national parks. These services gross more than $1 billion

every year and provide jobs for more than 25,000 people during peak season. The regulations at 36 CFR part 51 primarily implement Title IV of the National Parks Omnibus Management Act of 1998 (54 U.S.C., 101911 *et seq.,* also referred to as Pub. L. 105–391), which provides legislative authority, policies, and requirements for the solicitation, award, and administration of NPS concession contracts. Furthermore, 54 U.S.C. 101911 *et seq.,* provides that ''all proposed concession contracts shall be awarded by the Secretary to the person, corporation or other entity submitting the best proposal, as determined by the Secretary through a competitive selection process. Such competitive process shall include simplified procedures for small, individually-owned, concessions contracts.''

We utilize NPS Forms 10–356, 10–356A, 10–356B, 10–357A, 10–357B, 10–358, 10–359A, and 10–359B to collect the following types of information associated with the administration of concessions:

- Description of how respondent will conduct operations to minimize disturbance to wildlife; protect park resources; and provide visitors with a high quality, safe, and enjoyable visitor experience.
- Organizational structure and history and experience with similar operations.
- Details on violations or infractions and how they were handled.
- Financial information and demonstration that respondent has credible, proven track record of meeting obligations.

Addition to the forms, the following information is collected in narrative format: (1) Amendments, (2) Appeals, (3) Request to Construct a Capital Improvement, (4) Construction Report, (5) Application to Sell or Transfer Concession Operation, and (6) Recordkeeping.

Title of Collection: National Park Service Concessions, 36 CFR 51.

OMB Control Number: 1024–0029.

Form Number: NPS Forms 10–356, 10–356A, 10–356B, 10–357A, 10–357B, 10–358, 10–359A, and 10–359B.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals, businesses, and nonprofit organizations.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for proposals, amendments, and appeals; annually for financial reports; and ongoing for recordkeeping.

Total Estimated Annual Responses: 1,382.

Estimated Completion Time per Response: 0.5 hours to 800 hours depending on respondent and/or activity.

Total Estimated Annual Burden Hours: 159,892 hours.

Total Estimated Annual Nonhour Burden Cost: $425,000.

- $420,000 for proposals associated with expenses for printing, travel for onsite visits, and professional fees).
- $5,000 ($250 × 20 applications) for application to sell or transfer concession operation associated with preparing and submitting an application.

Activity	Total annual responses	Completion time per response (hours)	Total annual burden hours *
Concessioner Annual Financial Report			
Form 10–356, ''Concessioner Annual Financial Report''	150	15	2,250
Form 10–356A, ''Concessioner Annual Financial Report (For Concessioners with Gross Receipts Less than $500,000)''	350	4	1,400
Form 10–356B, ''Concessioner Annual Financial Report (For Concessioners with Special Accounts and Utility Add-ons)''	30	2	60
Proposals for Concession Opportunities			
Form 10–359A, ''Large Concession''	30	240	7,200
Form 10–359B, ''Small Concession''	60	80	4,800
Amendments	1	1	1
Appeals	1	.5	1
Request to Contruct a Capital Improvement			
Large Projects	31	16	496
Small Projects	89	8	712
Construction Report			
Large Project	31	56	1,736
Small Project	89	24	2,136
Recordkeeping			
Large Concessions	150	800	120,000
Small Concessions	350	50	17,500
Application to Sell or Transfer a Concession Operation	20	80	1,600
Totals:	1,382		159,892

* Rounded.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2022–09929 Filed 5–6–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0033848; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: History Fort Lauderdale (Formerly Fort Lauderdale Historical Society), Fort Lauderdale, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: History Fort Lauderdale, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to History Fort Lauderdale. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to History Fort Lauderdale at the address in this notice by June 8, 2022.

FOR FURTHER INFORMATION CONTACT: Tara Chadwick, History Fort Lauderdale, 219 SW 2nd Avenue, Fort Lauderdale, FL 33301, telephone (954) 463–4431, email *tchadwick@flhc.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of History Fort Lauderdale, Fort Lauderdale, FL, that meet the definition of objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1980, Frederick Anderson donated three lithic projectile points with a Michigan provenience to the Fort Lauderdale Historical Society (History Fort Lauderdale). In 2021, History Fort Lauderdale was contacted by the Tribal Historic Preservation Officer for the Bay Mills Indian Community, Michigan. According to information provided by the Bay Mills Indian Community, these projectile points are considered a sacred symbol of the Tribe's cultural identity. Based on consultation information provided by the Bay Mills Indian Community, History Fort Lauderdale has determined that these lithic items meet the definition of objects of cultural patrimony.

Determinations Made by History Fort Lauderdale

Officials of History Fort Lauderdale have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the three cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the objects of cultural patrimony and the Bay Mills Indian Community, Michigan.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Tara Chadwick, History Fort Lauderdale, 219 SW 2nd Avenue, Fort Lauderdale, FL 33301, telephone (954) 463–4431, email *tchadwick@flhc.org,* by June 8, 2022. After that date, if no additional claimants have come forward, transfer of control of the Bay Mills Indian Community, Michigan may proceed.

The History Fort Lauderdale is responsible for notifying the Bay Mills Indian Community, Michigan that this notice has been published.

Dated: April 27, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–09894 Filed 5–6–22; 8:45 am]

BILLING CODE 4312–52–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB) hereby gives notice of two corrected times in previously noticed meeting sessions. The original **Federal Register** notice appeared on May 2, 2022, at 87 FR 25680–81.

FOR FURTHER INFORMATION CONTACT: Ann Bushmiller, 703–292–8304.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 2, 2022, in FR Doc. 2022–09503, on page 25681, in the first column, correct the Plenary Board Meeting Open Session time to read: 10:30 a.m.–1:40 p.m. In the second column of the same page, correct the Plenary Board Meeting Open Session time to read: 1:30 p.m.–2:30 p.m.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–09981 Filed 5–5–22; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include assessment of the progress of awarded proposals. The majority of these meetings will take place at NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical

information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the **Federal Register**. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposal review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF website: *https://www.nsf.gov/events/*. This information may also be requested by telephoning, 703/292–8687.

Dated: May 4, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–09892 Filed 5–6–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of May 9, 16, 23, 30, June 6, 13, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of May 9, 2022

Tuesday, May 10, 2022

9:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines; (Contact: Kellee Jamerson: 301–415–7408)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Thursday, May 12, 2022

10:00 a.m. Briefing on Advanced Reactors Activities with Federal Partners; (Contact: Caty Nolan: 301–415–1535)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of May 16, 2022—Tentative

There are no meetings scheduled for the week of May 16, 2022.

Week of May 23, 2022—Tentative

There are no meetings scheduled for the week of May 23, 2022.

Week of May 30, 2022—Tentative

Wednesday, June 1, 2022

10:00 a.m. Transformation at the NRC—Sustaining Progress as Modern, Risk-Informed Regulator; (Contact: Aida Rivera-Varona: 301–415–4001)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Friday, June 3, 2022

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards; (Contact: Larry Burkhart: 301–287–3775)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of June 6, 2022—Tentative

There are no meetings scheduled for the week of June 6, 2022.

Week of June 13, 2022

Tuesday, June 14, 2022

10:00 a.m. Briefing on Human Capital and Equal Employment Opportunity; (Contact: Nicole Newton: 301–415–8316)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Thursday, June 16, 2022

10:00 a.m. Briefing on Results of the Agency Action Review Meeting; (Contact: Nicole Fields: 630–829–9570)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: May 5, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–10015 Filed 5–5–22; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0102]

Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB)

approval for an existing collection of information. The information collection is entitled, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.''

DATES: Submit comments by July 8, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0102. 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.
- *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0102 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0102.
- *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 supporting statement is available under ADAMS Accession No. ML22115A184.
- *NRC's PDR*: You may examine and purchase copies of public documents, by appointment, at the NRC's 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.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0102in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.
2. *OMB approval number:* 3150–0217.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* On occasion and annually.
6. *Who will be required or asked to respond:* Individuals and households; businesses and organizations; State, Local, or Tribal governments.
7. *The estimated number of annual responses:* 4,200.
8. *The estimated number of annual respondents:* 4.200.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1,087.5.
10. *Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, for the purpose of 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. Feedback collected under this generic clearance will provide useful information, but it will 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.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: May 4, 2022.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2022–09872 Filed 5–6–22; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Notices Following a Substantial Cessation of Operations

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information that is necessary to fulfill various reporting obligations following a cessation of operations at a facility. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before July 8, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.* Refer to OMB control number 1212–0073 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 20005–4026.

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 received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212–0073. All comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including any personal information provided. Commenters should not include any information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (''confidential business information''). Submission of confidential business information without a request for protected treatment constitutes a waiver of any claims of confidentiality.

Copies of the collection of information may be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or calling 202–229–4040 during normal business hours. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–229–6563. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Section 4062(e) of the Employee Retirement Income Security Act of 1974 (ERISA) imposes reporting obligations in the event of a ''substantial cessation of operations.'' A substantial cessation of operations occurs when a permanent cessation at a facility causes a separation from employment of more than 15 percent of all ''eligible employees.'' ''Eligible employees'' are employees eligible to participate in any of the facility's employer's employee pension benefit plans. Following a substantial cessation of operations, the facility's employer is treated, with respect to its single-employer pension plans covered by title IV of ERISA that are covering participants at the facility, as if the employer were a withdrawing substantial employer under a multiple employer plan. Under section 4063(a) of ERISA, the Pension Benefit Guaranty Corporation (PBGC) must receive notice of the substantial cessation of operations and a request to determine the employer's resulting liability.

To fulfill such resulting liability, the employer may elect, under section 4062(e)(4)(A), to make additional contributions annually for seven years to plans covering participants at the facility where the substantial cessation of operations took place. Under sections 4062(e)(4)(E)(i)(I), (II), (III), (IV), and (V) respectively, an employer that is making the election for annual additional contributions must give notice to PBGC of: (1) Its decision to make the election, (2) its payment of an annual contribution, (3) its failure to pay an annual contribution, (4) its receipt of a funding waiver from the Internal Revenue Service, and (5) the ending of its obligation to make additional annual contributions.

PBGC is requesting that OMB extend approval of a form series, consisting of Form 4062(e)–01, Form 4062(e)–02, Form 4062(e)–03, and Form 4062(e)–04, that is used to fulfill these reporting obligations. An employer or a plan administrator files Form 4062(e)–01 to notify PBGC of the occurrence of a substantial cessation of operations and request a determination of the employer's liability. An employer files Form 4062(e)–02 to notify PBGC that it made the elections to pay annual additional contributions to a plan. An employer files Form 4062(e)–03 to notify PBGC that it paid an annual additional contribution, received a funding waiver from the Internal Revenue Service, or is no longer obligated to pay additional annual contributions. Finally, an employer files Form 4062(e)–04 to notify PBGC that it failed to pay an additional annual contribution to the plan.

PBGC needs the information requested in the forms and notification (1) to determine an employer's liability to a plan following a substantial cessation of operations and (2) to ensure that an employer that made the election of additional annual contributions is fulfilling its payment obligations.

The collection of information has been approved by OMB under control number 1212–0073 (expires August 31, 2022). PBGC intends to request that

OMB extend its approval for another three years. 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.

PBGC estimates that, over the next 3 years, 5 forms in this series will be submitted each year. PBGC estimates that these forms would be completed by a combination of plan office staff and outside professionals: Attorneys and actuaries. PBGC estimates a total annual hour burden of 38.5 hours. PBGC estimates a total annual cost burden of $39,415.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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.

Issued in Washington, DC, by:

Stephanie Cibinic,

Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2022–09896 Filed 5–6–22; 8:45 am]

BILLING CODE 7709–02–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Request for Coverage Determination Form

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval, with modifications, under the Paperwork Reduction Act, of a collection of information necessary for PBGC to determine whether a plan is covered under title IV of the Employee Retirement Security Income Act of 1974.

DATES: Comments must be submitted by June 8, 2022.

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. A copy of the request will be posted on PBGC's website at *https://www.pbgc.gov/prac/laws-and-regulation/federal-register-notices-open-for-comment.* It may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC, 1200 K Street NW, Washington, DC 20005–4026; or, calling 202–229–4040 during normal business hours. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–229–6563. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information that filers use to request that PBGC determine whether a defined benefit pension plan is covered under title IV of the Employee Retirement Income Security Act of 1974 (ERISA). (OMB control number 1212–0072; expires June 30, 2022). This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

A plan is covered under title IV, and thereby insured by PBGC, if it is described in section 4021(a) of ERISA and does not meet one of the exemptions from coverage listed in section 4021(b)(1)–(13). If a question arises about whether a plan is covered under title IV, a plan may submit the Request for Coverage Determination form to PBGC.

The Request for Coverage Determination form and corresponding instructions are suitable for all types of requests, but they highlight the four plan types for which coverage determinations are most frequently requested: (1) Church plans as listed in section 4021(b)(3) of ERISA; (2) plans that are established and maintained exclusively for the benefit of plan sponsors' substantial owners as listed in section 4021(b)(9); (3) plans covering, since September 2, 1974, no more than 25 active participants that are established and maintained by professional services employers as listed in section 4021(b)(13); and (4) Puerto Rico-based plans within the meaning of section 1022(i)(1) of ERISA. PBGC needs the information requested to determine whether a plan is covered or not covered under title IV of ERISA.

PBGC intends to make editorial and formatting changes to question 1 and 2 of Part II of the form. These revisions are intended to provide greater clarity to filers. In addition, PBGC plans to add a new question to Part II inquiring about the number of eligible participants with no accrued benefit. This addition is intended to garner a more accurate count of a plan's participants. Finally, PBGC plans to amend Question 4 of Part III applicable to a plan seeking a determination as a substantial owners plan. Under the amendment, a plan will need to provide the dates when participants separated from service, in addition to dates and amounts of payment to them. This addition is intended to allow PBGC to properly count payees who may still be participants in a plan even after distributions have occurred.

The collection of information has been approved under OMB control number 1212–0072 (expires June 31, 2022). On March 1, 2022, PBGC published in the **Federal Register** (at 87 FR 11492) a notice informing the public of its intent to request approval of the revised collection of information. PBGC did not receive any comments. 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.

PBGC estimates that each year there will be 310 Request for Coverage Determination forms submitted to PBGC. PBGC further estimates the average hour burden is 1.5 hours and average cost burden is $300. The total estimated annual burden of the collection of information is 465 hours and $93,000

Issued in Washington, DC, by.

Stephanie Cibinic,

Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2022–09895 Filed 5–6–22; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2022–58; Order No. 6165]

Competitive Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent filing by the Postal Service of specific rates for its Inbound Letter Post Small Packets and Bulky Letters product effective January 1, 2023. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 13, 2022.

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

I. Introduction

On April 29, 2022, the Postal Service filed a notice of rates not of general applicability for Inbound Letter Post Small Packets and Bulky Letters (Inbound E-format Letter Post) effective January 1, 2023.[1] The Postal Service requests that the Commission favorably review the proposed prices so that the Postal Service may submit the prices to the Universal Postal Union (UPU) before the June 1, 2022 deadline. Notice at 5.

II. Contents of Filing

In its Notice, the Postal Service proposes new prices for the Inbound Letter Post Small Packets and Bulky Letters product. *Id.* at 2. Under the UPU, by June 1, 2022, the Postal Service may submit self-declared rates for Inbound Letter Post Small Packets and Bulky Letters that would take effect on January 1, 2023.[2] The Postal Service states that the proposed prices comply with 39 U.S.C. 3633. Notice at 4. To support its proposed Inbound Letter Post Small Packets and Bulky Letters prices, the Postal Service filed the proposed prices; a copy of the certification required under 39 CFR 3015.5(c)(2); and a redacted copy of Governors' Decision No. 19–1. *Id.* at 5; *see id.* Attachments 2–4. The Postal Service also filed redacted financial workpapers. Notice at 5.

In addition, the Postal Service filed an unredacted copy of Governors' Decision No. 19–1, the unredacted new prices, and related financial information under seal. *Id.* at 4–5. The Postal Service also provided an application for non-public treatment of materials filed under seal filed pursuant to 39 CFR part 3011. *Id.* at 4; *see id.* Attachment 1.

III. Administrative Actions

The Commission establishes Docket No. CP2022–58 for consideration of matters raised by the Notice and appoints Katalin K. Clendenin to serve as Public Representative in this docket. The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, and 39 CFR 3035.105 and .107. Comments are due no later than May 13, 2022. The public portions of the filing can be accessed via the Commission's website (*http://www.prc.gov*).

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2022–58 for consideration of the matters raised by the Postal Service's Notice.

2. Comments are due no later than May 13, 2022.

3. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin will serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these dockets.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–09851 Filed 5–6–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of the United States Postal Service of Rates Not of General Applicability for Inbound E-Format Letter Post, and Application for Non-Public Treatment, April 29, 2022, at 1 (Notice).

[2] *Id.;* Universal Postal Convention (UPU Convention) Article 29.1. The UPU Convention is available at, *https://www.upu.int/UPU/media/upu/files/aboutUpu/acts/actsOfCurrentCycle/actsLastCongressActsEn.pdf.*

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–147, OMB Control No. 3235–0131]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Rule 17a–7

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–7 (17 CFR 240.17a–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–7 requires a non-resident broker-dealer (generally, a broker-dealer with its principal place of business in a place not subject to the jurisdiction of the United States) registered or applying for registration pursuant to Section 15 of the Exchange Act to maintain—in the United States—complete and current copies of books and records required to be maintained under any rule adopted under the Exchange Act and furnish to the Commission a written notice specifying the address where the copies are located. Alternatively, Rule 17a–7 provides that non-resident broker-dealers may file with the Commission a written undertaking to furnish the requisite books and records to the Commission upon demand within 14 days of the demand.

There are approximately 30 non-resident brokers and dealers. Based on the Commission's experience, the Commission estimates that the average amount of time necessary to comply with Rule 17a–7 is one hour per year. Accordingly, the total industry-wide reporting burden is approximately 30 hours per year. Assuming an average cost per hour of approximately $319 for a compliance manager, the total internal

cost of compliance for the respondents is approximately $9,570 per year.[1]

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (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. Consideration will be given to comments and suggestions submitted by July 8, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: May 3, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09845 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, May 12, 2022.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b.)

Dated: May 5, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–10029 Filed 5–5–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94841; File No. SR–MEMX–2022–02]

Self-Regulatory Organizations; MEMX LLC; Notice of Withdrawal of a Proposed Rule Change To Amend the Exchange's Fee Schedule to Adopt Connectivity Fees

May 3, 2022.

On March 1, 2022, MEMX LLC (''MEMX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its Fee Schedule to adopt Connectivity Fees. The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3] The proposed rule change was published for comment in the **Federal Register** on March 21, 2022.[4] On April 29, 2022, MEMX withdrew the proposed rule change (SR–MEMX–2022–02).[5]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09858 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94835; File No. SR–NYSE–2021–44]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Withdrawal of Proposed Rule Change To Amend NYSE Rules 7.31, 7.35, 7.35B, 7.35C, 98, and 104 Relating to the Closing Auction

May 3, 2022.

On September 3, 2021, New York Stock Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Exchange Rules 7.31 (Orders and Modifiers), 7.35 (General), 7.35B (DMM-Facilitated Closing Auctions), 7.35C (Exchange-Facilitated Auctions), 98 (Operation of a DMM Unit), and 104 (Dealings and Responsibilities of DMMs) relating to the Closing Auction. The proposed rule change was published for comment in the **Federal Register** on September 22, 2021.[3]

On November 1, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to

[1] $319 per hour for a compliance manager is from SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by Commission staff for an 1800-hour work-year, multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead, and adjusted for inflation.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as ''establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.'' 15 U.S.C. 78s(b)(3)(A)(ii).

[4] *See* Securities Exchange Act Release No. 94419 (March 15, 2022), 87 FR 16046.

[5] *See* Letter from Anders Franzon, General Counsel, MEMX, to Vanessa Countryman, Secretary, Commission, dated April 29, 2022.

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93037 (Sept. 16, 2021), 86 FR 52719 (Sept. 22, 2021) (SR–NYSE–2021–44).

[4] 15 U.S.C. 78s(b)(2).

determine whether to approve or disapprove the proposed rule change to December 21, 2021.[5] On December 17, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7] On March 17, 2022, the Commission extended the time for Commission action on proceedings to approve or disapprove the proposed rule change to May 20, 2022.[8] The Commission received two comment letters on the proposal.[9]

On April 26, 2022, the Exchange withdrew the proposed rule change (File No. SR–NYSE–2021–44).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09852 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94836; File No. SR–MIAX–2022–17]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange, LLC to Amend Exchange Rule 518, Complex Orders and Exchange Rule 515, Execution of Orders and Quotes, To Permit Pricing of Stock-Option Complex Strategies in any Decimal Price the Exchange Determines

May 3, 2022.

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 April 19, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') 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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend its Rulebook to permit pricing of stock-option complex strategies in any decimal price the Exchange determines.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 518, Complex Orders, and Exchange Rule 515, Execution of Orders and Quotes, to permit pricing of stock-option complex strategies in any decimal price the Exchange determines.[3]

Background

In October 2016, the Exchange adopted rules governing the trading in, and detailing the functionality of the MIAX Options System[4] in the handling of complex orders on the Exchange.[5] The Exchange defines a ''complex order'' as any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the ''legs'' or ''components'' of the complex order), for the same account, in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purposes of executing a particular investment strategy. Mini-options may only be part of a complex order that includes other mini-options. Only those complex orders in the classes designated by the Exchange and communicated to Members[6] via Regulatory Circular with no more than the applicable number of legs, as determined by the Exchange on a class-by-class basis and communicated to Members via Regulatory Circular,[7] are eligible for processing.[8]

A complex order can also be a ''stock-option order'' as described further, and subject to the limitations set forth, in Interpretations and Policies .01 of Exchange Rule 518. A stock-option order is an order to buy or sell a stated number of units of an underlying security (stock or Exchange Traded Fund Share (''ETF'')) or a security convertible into the underlying stock (''convertible security'') coupled with the purchase or sale of options contract(s) on the opposite side of the market representing either (i) the same number of units of the underlying security or convertible security, or (ii) the number of units of the underlying stock necessary to create a delta neutral position, but in no case in a ratio greater

[5] *See* Securities Exchange Act Release No. 93488 (Nov. 1, 2021), 86 FR 61352 (Nov. 5, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 93809 (Dec. 17, 2021), 86 FR 73060 (Dec. 23, 2021).

[8] *See* Securities Exchange Act Release No. 94457 (Mar. 17, 2022), 87 FR 16539 (Mar. 23, 2022).

[9] *See* Anonymous Letter (Sept. 27, 2021); Letter from Richard Grant, General Counsel, GTS Securities LLC, to J. Matthew DeLesDernier, Assistant Secretary, Commission (Mar. 16, 2022). The comments received are available at *https://www.sec.gov/comments/sr-nyse-2021-44/srnyse202144.htm.*

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange notes that other options exchanges offer this pricing increment for stock-option orders. *See* Cboe Options Rule 5.33(f)(i)(B), which provides that, ''users may express bids and offers for a stock-option order (including a QCC with Stock Order) in any decimal price the Exchange determines. The minimum increment for the option leg(s) of a stock-option order is $0.01 or greater, which the Exchange may determine on a class-by-class basis, regardless of the minimum increments otherwise applicable to the option leg(s), and the stock leg of a stock-option order may be executed in any decimal price permitted in the equity market.'' *See* also Nasdaq ISE Options 3, Section 14(c)(1), which similarly provides, ''bids and offers for Complex Options Strategies may be expressed in one cent ($0.01) increments, and the options leg of Complex Options Strategies may be executed in one cent ($0.01) increments, regardless of the minimum increments otherwise applicable to the individual options legs of the order. Bids and offers for Stock-Option Strategies or Stock-Complex Strategies may be expressed in any decimal price determined by the Exchange, and the stock leg of a Stock-Option Strategy or Stock-Complex Strategy may be executed in any decimal price permitted in the equity market. The options leg of a Stock-Option Strategy or Stock-Complex Strategy may be executed in one cent ($0.01) increments, regardless of the minimum increments otherwise applicable to the individual options legs of the order.'' *See* also Cboe EDGX Rule 21.20(f)(1)(B).

[4] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[5] *See* Securities Exchange Act Release No. 79072 (October 7, 2016), 81 FR 71131 (October 14, 2016)(SR–MIAX–2016–26).

[6] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[7] *See* MIAX Regulatory Circular 2016–41, Trading of Complex Orders on MIAX (October 14, 2016) available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_RC_2016_41.pdf.*

[8] *See* Exchange Rule 518(a)(5).

than eight-to-one (8.00), where the ratio represents the total number of units of the underlying security or convertible security in the option leg to the total number of units of the underlying security or convertible security in the stock leg. Only those stock-option orders in the classes designated by the Exchange and communicated to Members via Regulatory Circular with no more than the applicable number of legs as determined by the Exchange on a class-by-class basis and communicated to Members via Regulatory Circular,[9] are eligible for processing.[10]

Additionally, the Exchange offers a Complex Qualified Contingent Cross Order or ''cQCC'' Order which is comprised of an originating complex order to buy or sell where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, as defined in Rule 516, Interpretations and Policies .01,[11] coupled with a contra-side complex order or orders totaling an equal number of contracts. The trading of cQCC Orders is governed by Rule 515(h)(4).[12]

Exchange Rule 515(h)(4) currently provides that, cQCC Orders, as defined in Rule 518(b)(6), are automatically executed upon entry provided that, with respect to each option leg of the cQCC Order, the execution (i) is not at the same price as a Priority Customer Order on the Exchange's Book; and (ii) is at or between the NBBO. The System will reject a cQCC Order if, at the time of receipt of the cQCC Order: (i) the strategy is subject to a cPRIME Auction pursuant to Rule 515A, Interpretation and Policy .12 or to a Complex Auction pursuant to Rule 518(d); or (ii) any component of the strategy is subject is subject to a SMAT Event as described in Rule 518(a)(16). Further paragraph (A) of Exchange Rule 515(h)(4) provides that cQCC Orders will be automatically canceled if they cannot be executed. Paragraph (B) of Exchange Rule 515(h)(4) provides that, cQCC Orders may only be entered in the minimum trading increments applicable to complex orders under Rule 518(c)(1)(i). Paragraph (C) of Exchange Rule 515(h)(4) provides that, the Exchange will determine on a class-by-class basis, the option classes in which cQCC Orders are available for trading on the Exchange, and will announce such classes to Members via Regulatory Circular.

Trading of complex orders on the Exchange is governed by Exchange Rule 518, Complex Orders. Minimum increments and trade prices for complex orders are described in current subparagraph (i) of Rule 518(c)(1) which states, bids and offers on complex orders and quotes may be expressed in $0.01 increments, and the component(s) of a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to individual components of the complex order. Current subparagraph (ii) of Exchange Rule 518(c)(1) states, if any component of a complex strategy would be executed at a price that is equal to a Priority Customer [13] bid or offer on the Simple Order Book,[14] at least one other component of the complex strategy must trade at a price that is better than the corresponding MBBO.[15] Current subparagraph (iii) of Exchange Rule 518(c)(1) states, a complex order will not be executed at a net price that would cause any component of the complex strategy to be executed: (A) At a price of zero; or (B) ahead of a Priority Customer order on the Simple Order Book without improving the MBBO of at least one component of the complex strategy. Current subparagraph (iv) of Exchange Rule 518(c)(1) states, a complex order or eQuote (as defined in Interpretations and Policies .02 of Rule 518) will not be executed at a price that is outside of its MPC Price (as defined in Interpretations and Policies .05(f) of Rule 518) or its limit price.[16]

Proposal

The Exchange now proposes to (i) amend its rule pertaining to the pricing of complex orders to permit the pricing of stock-option complex strategies in any decimal price the Exchange determines; and (ii) make additional changes to the Exchange's rulebook necessary to support the implementation of the proposed pricing structure.

Rule 518 Complex Orders

Specifically, the Exchange proposes to amend subsection (c)(1) Minimum Increments and Trade Prices of Rule 518, to adopt new paragraph (ii), and to renumber current paragraph (c)(1)(ii) as paragraph (c)(1)(iii). New paragraph (c)(1)(ii) will provide that bids and offers on complex orders, quotes, and RFR Responses for stock-option complex strategies (including a cQCC Order entered with a stock component) may be expressed in any decimal price the Exchange determines. The option component(s) of such a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to individual components of the complex order, and the stock component of such a complex order may be executed in any decimal price permitted in the equity market. Minimum increments less than $0.01 are appropriate for stock-option orders as the stock component can trade at finer decimal increments permitted by the equity market.[17] Furthermore, the Exchange notes that even with the flexibility provided in the proposed rule, the individual options and stock legs must trade at increments allowed by the Commission in the options and equities markets.

To support the pricing of stock-option orders in any decimal price the Exchange determines, the Exchange is proposing to make a number of conforming changes throughout its Rulebook to clearly differentiate pricing and support of complex strategies with only option components, (which remains unchanged under this proposal in $0.01 increments), and pricing and support of stock-option complex strategies which may be in sub-penny increments, as determined by the Exchange.

Therefore, the Exchange proposes to make a minor conforming change to the

[9] *See* MIAX Regulatory Circular 2018–34, Implementation of Stock-Option Complex Order Trading on the Exchange (August 2, 2018) available at *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2018_34.pdf.*

[10] *See supra* note 8.

[11] A ''qualified contingent trade'' is a transaction consisting of two or more component orders, executed as agent or principal, where: (a) At least one component is an NMS Stock, as defined in Rule 600 of Regulation NMS under the Exchange Act; (b) all components are effected with a product or price contingency that either has been agreed to by all the respective counterparties or arranged for by a broker-dealer as principal or agent; (c) the execution of one component is contingent upon the execution of all other components at or near the same time; (d) the specific relationship between the component orders (*e.g.,* the spread between the prices of the component orders) is determined by the time the contingent order is placed; (e) the component orders bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or cancelled; and (f) the transaction is fully hedged (without regard to any prior existing position) as a result of other components of the contingent trade. *See* Interpretations and Polices .01 of Exchange Rule 516.

[12] *See* Exchange Rule 518(b)(6).

[13] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 100.

[14] The term ''Simple Order Book'' is the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 518(a)(15).

[15] The term ''MBBO'' means the best bid or offer on the Simple Order Book on the Exchange. *See* Exchange Rule 518(a)(13).

[16] *See* Exchange Rule 518(c)(1).

[17] The Exchange notes that its rule text is substantially similar to the rules of other exchanges that trade stock-option orders. *See supra* note 3.

rule text of current paragraph (c)(1)(ii) of Rule 518, which will be renumbered as paragraph (c)(1)(iii). The current rule text states that if any component of a complex strategy would be executed at a price that is equal to a Priority Customer bid or offer on the Simple Order Book, at least one other component of the complex strategy must trade at a price that is better than the corresponding MBBO. The Exchange now proposes to amend the rule to add additional detail and specificity by stating that, if any component of a complex strategy would be executed at a price that is equal to a Priority Customer bid or offer on the Simple Order Book, at least one other option component of the complex strategy must trade at a price that is better than the corresponding MBBO. The Exchange believes that clarifying that the component of the complex strategy must be an option component adds additional detail to the rule and makes it clear in the Exchange's rules that a Priority Customer bid or offer must be improved by at least $0.01 by the option component of either a complex strategy with only option components or the option component of a stock-option complex strategy.

Additionally, the Exchange proposes to amend paragraph (i) of subsection (c)(1), Minimum Increments and Trade Prices, of Exchange Rule 518, to add additional detail and clarity to the rule text. Currently, the rule provides that, bids and offers on complex orders and quotes may be expressed in $0.01 increments, and the component(s) of a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to individual components of the complex order. The Exchange now proposes to amend the rule text to provide that, bids and offers on complex orders, quotes, and RFR Responses for complex strategies having only option components may be expressed in $0.01 increments, and the component(s) of such a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to individual components of the complex order.

Paragraph (c)(1)(i) pertains to complex strategies that have only option components (as opposed to paragraph (c)(1)(ii) which pertains to stock-option complex strategies) and therefore provides that bids, offers, and RFR Responses for complex strategies having only option components may be expressed in $0.01 increments. The Exchange believes this change is necessary to differentiate between which strategies are required to be priced in $0.01 increments (complex strategies having only option components) and which strategies may be priced in an increment other than $0.01 (stock-option complex strategies). The Exchange believes this amendment provides additional detail and clarity regarding the pricing of complex strategies having only option components, which is not changing under this proposal.

The Exchange also proposes to amend the rule text of current paragraph (c)(1)(iii) of Rule 518 to make two minor conforming changes and to renumber the paragraph as new paragraph (c)(1)(iv). Currently, the rule states that, a complex order will not be executed at a net price that would cause any component of the complex strategy to be executed: (A) At a price of zero; or (B) ahead of a Priority Customer order on the Simple Order Book without improving the MBBO of at least one component of the complex strategy. The Exchange now proposes to add additional detail and specificity to the rule to state that, a complex order will not be executed at a net price that would cause any option component of the complex strategy to be executed: (A) at a price of zero; or (B) ahead of a Priority Customer order on the Simple Order Book without improving the MBBO of at least one option component of the complex strategy.[18] The Exchange believes that clarifying that the component of the complex strategy must be an option component adds additional detail and clarity to the rule. The Exchange also proposes to make a non-substantive change to existing paragraph (c)(1)(iv) to renumber the paragraph as (c)(1)(v).

The Exchange proposes to amend subparagraph (i) of section (c)(4), Managed Interest Process for Complex Orders, of Rule 518 to add additional detail and clarity to the rule text. The managed interest process for complex orders ensures that a complex order will never be executed at a price that is through the individual component prices on the Simple Order Book.

Currently, the rule provides that, when the opposite side icMBBO[19] includes a Priority Customer Order, the System will book and display such booked complex order on the Strategy Book[20] at a price (the ''book and display price'') that is $0.01 away from the current opposite side icMBBO. The Exchange proposes to amend the rule text to provide that, when the opposite side icMBBO includes a Priority Customer Order, the System will book and display such booked complex order on the Strategy Book at a price (the ''book and display price'') such that at least one option component is priced $0.01 away from the current opposite side MBBO. The MBBO is comprised of the best bid and the best offer on the Simple Order Book on the Exchange.[21]

This change supports the proposed change to 518(c)(1)(iii) which provides that if any component of a complex strategy would be executed at a price that is equal to a Priority Customer bid or offer on the Simple Order Book, at least one option component of the complex strategy must trade at a price that is better than the corresponding MBBO. Together, these changes ensure that no complex strategy (either a complex strategy with only option components or a stock-option complex strategy) will execute ahead of a Priority Customer order on the Simple Order Book without improving the MBBO of at least one option component of the complex strategy by at least $0.01.[22] The Exchange believes this change provides additional detail and clarity regarding the managed interest process for complex strategies with only option components and for stock-option complex strategies, and harmonizes the rule text to the System behavior.

The Exchange proposes to amend paragraph (d)(4), RFR Response, of Rule 518 to make a conforming change to the rule necessary to support pricing of stock-option complex strategies in any decimal price determined by the Exchange. Currently, Rule 518(d)(4) provides that, RFR responses may be submitted in $0.01 increments. The Exchange proposes to amend this provision to provide that RFR Responses may be submitted in the increments defined in proposed subparagraphs (c)(1)(i) and (c)(1)(ii) of this Rule. This proposed change is consistent with the proposed change to Rule 518(c)(1), Minimum Increments and Trade Prices, as described above, and aligns the pricing of complex strategies with only option components in $0.01, which is not changing under this proposal, and the pricing of

[18] The Exchange proposes to make an identical conforming change to paragraph (d)(6) of Rule 518.

[19] The icMBBO is a calculation that uses the best price from the Simple Order Book for each component of a complex strategy including displayed and non-displayed trading interest. For stock-option orders, the icMBBO for a complex strategy will be calculated using the best price (whether displayed or non-displayed) on the Simple Order Book in the individual option component(s), and the NBBO in the stock component. *See* Exchange Rule 518(a)(11).

[20] The ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(17).

[21] *See supra* note 15.

[22] *See* Exchange Rule 518(c)(1)(iv) as proposed herein.

complex strategies with an option component in any decimal price the Exchange determines as proposed herein. RFR responses submitted for a complex strategy having only options components may be expressed in $0.01 increments as proposed in subparagraph (c)(1)(i), whereas RFR responses submitted for a stock-option complex strategy may be expressed in any decimal price the Exchange determines as proposed in subparagraph (c)(1)(ii). This change aligns RFR responses for complex strategies with only options components to the current price interval for complex orders of $0.01, which is not changing under this proposal, and aligns the pricing interval for stock-option complex strategies with the proposed change discussed herein to be in any decimal price as determined by the Exchange.[23]

The Exchange proposes to amend paragraph (d)(6)(i) of Rule 518 to add additional detail and clarity to the operation of the rule necessary to support pricing of stock-option complex strategies in sub-penny increments and clarify that the pricing and processing of complex strategies with only option components will remain unchanged under this proposal. Currently, the rule states that, at the conclusion of the Response Time Interval, Complex Auction-eligible orders will be priced and executed as follows, and allocated pursuant to subparagraph (7) of Rule 518: [24] (i) Using $0.01 inside the current icMBBO as the boundary (the ''boundary''), the System will calculate the price where the maximum quantity of contracts can trade and also determine whether there is an imbalance.[25]

The Exchange now proposes to amend the rule text to state that, at the conclusion of the Response Time Interval, Complex Auction-eligible orders will be priced and executed as follows, and allocated pursuant to subparagraph (7) of Rule 518: (i) Using $0.01 inside the current icMBBO for complex strategies with only option components or using a decimal price increment (as determined by the Exchange) inside the current icMBBO for stock-option complex strategies as the boundary (the ''boundary'') the System will calculate the price where the maximum quantity of contracts can trade and also determine whether there is an imbalance. This proposed change is consistent with the proposed change to Rule 518(c)(1), Minimum Increments and Trade Prices, as described above and allows the Exchange to accurately calculate prices for stock-option complex strategies. Using the same pricing increments that each complex strategy is priced in ($0.01 for complex strategies with only option components and the decimal price increment as determined by the Exchange for stock-option complex strategies) ensures that there are no calculation or rounding errors which ensures the accuracy and integrity of the Exchange's price calculations and the System's determination of the price where the maximum quantity of contracts can trade and also the System's determination of an imbalance. The Exchange believes this change adds additional detail and clarity to the rule, by clarifying current behavior as it relates to complex strategies with only option components and facilitates the proposed change to permit pricing of complex strategies with an option component in any decimal price the Exchange determines.

The Exchange proposes to amend paragraph (d)(6)(i)(A)2.a. of Rule 518 to provide for calculations in $0.01 increments to support complex strategies with only option components and to provide for calculations in any decimal price increment as determined by the Exchange to support stock-option complex strategies. Currently, the rule provides that, if the midpoint price is not in a $0.01 increment, the System will round toward the midpoint of the dcMBBO [26] to the nearest $0.01. The Exchange now proposes to amend the rule text to state that, for complex strategies with only option components if the midpoint price is not in a $0.01 increment, the System will round toward the midpoint of the dcMBBO to the nearest $0.01; for stock-option complex strategies, if the midpoint price is not in a decimal price increment as determined by the Exchange, the System will round toward the midpoint of the dcMBBO to the nearest decimal price increment as determined by the Exchange.

Similarly, the Exchange also proposes to amend paragraph (d)(6)(i)(A)2.b. of Rule 518 to provide for calculations in $0.01 increments to support complex strategies with only option components and to provide for calculations in any decimal increment as determined by the Exchange to support stock-option complex strategies. Currently, the rule provides that if the midpoint of the highest and lowest prices is also the midpoint of the dcMBBO and is not in a $0.01 increment the System will round the price up to the next $0.01 increment. The Exchange now proposes to amend the rule text to state that, if the midpoint of the highest and lowest prices is also the midpoint of the dcMBBO and is not in a $0.01 increment for complex strategies with only option components or in a decimal price increment as determined by the Exchange for stock-option complex strategies, the System will round the price up to the next $0.01 increment for complex strategies with only option components or to a decimal price increment as determined by the Exchange for stock-option complex strategies.

To properly perform the internal calculations described in Exchange Rule 518(d)(6)(i)(A)2.a. and b. correctly it is imperative that the decimal increment being used in the calculation properly aligns to the decimal quoting increment being used on the Exchange for that strategy, be it for complex strategies with only options components or stock-option complex strategies. Using the appropriate decimal increment that the strategy is priced in ($0.01 for complex strategies with only options components or any decimal price as determined by the Exchange for stock-option complex strategies) ensures that the Exchange accurately calculates the Auction Start Price to the proper decimal precision for either complex strategies with only options components (which may only be in $0.01 increments) or stock-option complex strategies (which may be in any price increment as determined by the Exchange). The Exchange believes these changes provide additional detail and clarification regarding the differentiation in calculations for complex strategies with only options components that are priced in $0.01 increments, which remains unchanged under this proposal, and calculations for stock-option complex strategies, which may be priced in increments other than $0.01. This change is necessary to support the proposed change discussed herein to price stock-option strategies in any decimal price increment as determined by the Exchange.

Rule 515 Execution of Orders and Quotes

Customer to Customer Cross Orders

The Exchange proposes to amend paragraph (h), Crossing Orders, of Rule

[23] The Exchange proposes to make an identical conforming change to Rule 518(e) for cLEP Responses.

[24] *See* Exchange Rule 518(d)(6).

[25] *See* Exchange Rule 518(d)(6)(i).

[26] The dcMBBO is calculated using the best displayed price for each component of a complex strategy from the Simple Order Book. For stock-option orders, the dcMBBO for a complex strategy will be calculated using the Exchange's best displayed bid or offer in the individual option component(s) and the NBBO in the stock component. *See* Exchange Rule 518(a)(8).

515, to clarify that Complex Customer Cross (''cC2C'') pricing is not changing under this proposal. Currently, subparagraph (B) of paragraph (3), of Rule 515(h), Complex Customer Cross (''cC2C'') Orders provides that cC2C Orders [27] may only be entered in the minimum trading increments applicable to complex orders under Rule 518(c)(1)(i). Current Rule 518(c)(1)(i) provides that the minimum trading increments applicable to complex orders is $0.01.[28] The Exchange proposes to amend subparagraph (B) to state that, cC2C Orders may only be entered in minimum trading increments of $0.01.

Complex Qualified Contingent Cross Orders

cQCC Orders [29] may be entered into the Exchange's System with a stock component or without the stock component. To support and facilitate the pricing proposal for stock-option strategies as proposed herein, a cQCC entered without the stock component will be treated as a complex strategy with only option components for pricing purposes (pricing in $0.01 increments only), whereas a cQCC entered with the stock component will be treated as a complex strategy with a stock component under the Exchange's new quoting structure as proposed herein. Therefore, the Exchange proposes to amend subparagraph (B) of paragraph (4), Complex Qualified Contingent Cross (''cQCC'') Orders to provide that cQCC Orders may only be entered in the minimum trading increments applicable to complex orders under proposed Rule 518(c)(1)(i) or 518(c)(1)(ii) if the cQCC Order includes the stock component upon entry.

Additionally, the Exchange proposes to adopt new subparagraph (D) to paragraph (4) of Rule 515(h) to provide a more fulsome description of cQCC Order handling of a cQCC Order entered without the stock component and a cQCC Order entered with the stock component. New subparagraph (D) will provide that, a cQCC Order may be entered with or without the stock component. A cQCC Order entered without the stock component will be treated as a complex strategy with only option components. A cQCC Order entered with the stock component shall be subject to Rule 518.01. A Member that submits a cQCC Order to the Exchange (with or without the stock component) represents that such order satisfies the requirements of a qualified contingent trade (as described in Interpretations and Policies .01 of Rule 516) and agrees to provide information to the Exchange related to the execution of the stock component as determined by the Exchange and communicated via Regulatory Circular.[30]

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [31] in general, and furthers the objectives of Section 6(b)(5) of the Act [32] in particular, in that it is 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change benefits investors and promotes just and equitable principles of trade because it provides investors with the ability to price stock-option complex strategies with greater precision.[33] This provides investors with greater opportunities for execution as it allows for more accurate pricing of stock-option complex strategies. The net price of a complex strategy with a stock component may result in a price that is accurately expressed in a finer decimal increment than $0.01 as a result of the stock ratio being used.

Example 1 Stock-Option Complex Strategy

The current market is:

MBBO XYZ Jan 15 Put 0.95 (10) × 1.00 (10)

NBBO XYZ Stock 20.00 (100) × 20.01 (100)

Customer strategy:

A customer order to Buy 1 XYZ Jan 15 Put and Buy 33 Shares of XYZ is received. The customer would like to pay $1.00 for the option and pay $20.01 for the stock for a net price $7.6033 as per the calculation of the strategy market below.

The market for the Strategy is:

*Strategy Bid = (Option Bid * Option Ratio) + (Stock Bid * Stock Ratio/100)*
*Strategy Bid = (0.95 * 1) + (20.00 * .33)*
Strategy Bid = 7.5500
*Strategy Ask = (Option Ask * Option Ratio) + (Stock Ask * Stock Ratio/100)*
*Strategy Ask = (1.00 * 1) + (20.01 * .33)*
Strategy Ask = 7.6033
Strategy market = 7.5500 × 7.6033

As the Exchange does not support stock option strategies priced in four decimal increments this strategy would be sent to a venue that supports four decimal pricing for execution.

Under the Exchange's proposal to permit stock-option complex strategies to be expressed in any decimal price as determined by the Exchange, if the Exchange determines to price stock-option complex strategies in $0.0001 increments, the above strategy could be placed on the Exchange's Strategy Book at its calculated net price. The customer who would like to pay $1.00 for the option and pay $20.01for the stock can now pay $1.00 for the option and pay $20.01 for the stock for a net price of $7.6033 as per the calculation above.

Pricing stock-option complex strategies in sub-penny increments permits more precision pricing and allows for complex strategies with a stock component to be effectively traded on the Exchange. Currently, firms that wish to execute these types of strategies will not send them to the MIAX Exchange due to the current System limitation which constrains the price to two decimal places, whereas the strategy may be more precisely priced in sub-penny increments on exchanges that permit sub-penny pricing of stock-option complex strategies to four decimal places.[34]

Further, the Exchange believes that the proposed rule change removes

[27] A Complex Customer Cross or ''cC2C'' Order is comprised of one Priority Customer complex order to buy and one Priority Customer complex order to sell at the same price and for the same quantity. Trading of cC2C Orders is governed by Rule 515(h)(3). *See* Exchange Rule 518(b)(5).

[28] Bids and offers on complex orders and quotes may be expressed in $0.01 increments, and the component(s) of a complex order may be executed in $0.01 increments, regardless of the minimum increments otherwise applicable to individual components of the complex order. *See* Exchange Rule 518(c)(1)(i).

[29] A Complex Qualified Contingent Cross or ''cQCC'' Order is comprised of an originating complex order to buy or sell where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, as defined in Rule 516, Interpretations and Policies .01, coupled with a contra-side complex order or orders totaling an equal number of contracts. Trading of cQCC Orders is governed by Rule 515(h)(4). *See* Exchange Rule 518(b)(6).

[30] *See* proposed Rule 515(h)(4)(D) and *see also* MIAX Options Regulatory Circular 2019–19, Update regarding Regulatory Requirements when entering a Qualified Contingent Cross Order (''QCC'') or a Complex Qualified Contingent Cross Order (''cQCC'') (March 19, 2019) available at: *https://www.miaxoptions.com/sites/default/files/circular-files/MIAX_Options_RC_2019_19.pdf.*

[31] 15 U.S.C. 78f(b).

[32] 15 U.S.C. 78f(b)(5).

[33] The Exchange notes that other options exchanges permit stock-option orders to be priced in decimal increments. *See* Cboe Options Rule 5.33(f)(i)(B), Nasdaq ISE Options 3, Section 14(c)(1), and Cboe EDGX Rule 21.20(f)(1)(B).

[34] *See id.*

impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by offering similar functionality to Members that can be found on other competing option exchanges.[35] Competition benefits investors by providing investors an additional venue to choose from when making order routing decisions.

Additionally, the Exchange believes its proposal to leave Complex Customer Cross Order functionality unchanged promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, to protects investors and the public interest. A Complex Customer Cross Order is comprised of one Priority Customer complex order to buy and one Priority Customer complex order to sell at the same price and for the same quantity.[36] Complex Customer Cross Orders are not exposed to the marketplace and are executed upon entry, provided that the execution is at least $0.01 better than the icMBBO, or the best net price of a complex order on the Strategy Book, whichever is more aggressive.[37] The Exchange believes that requiring a minimum improvement of $0.01 benefits investors and the public interest as it is not a de minimis price improvement amount. Further, the Exchange does not believe that Members on the Exchange are disadvantaged in any way by not being able to execute Complex Customer Cross Orders with a stock component in a sub-penny interval, as Members may use the cQCC Order type for stock-option complex strategies, or expose their stock-option complex strategy order to the market via the Exchange's cPRIME for price improvement in sub-penny increments.

To support the pricing of stock-option orders in any decimal price the Exchange determines, the Exchange is proposing to make a number of non-substantive conforming changes throughout its rules to clearly differentiate pricing and support of complex strategies with only option components, (which remains unchanged under this proposal in $0.01 increments), and pricing and support of stock-option complex strategies, which may be in any decimal price the Exchange determines. The Exchange believes that its proposed non-substantive changes to add additional detail and clarity to the Exchange's rulebook benefits investors and the public interest as it provides transparency and eliminates the potential for confusion regarding the operation of the Exchange's rules.

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 purposes of the Act. The Exchange does not believe that its proposal will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because all Members of the Exchange that transact stock-option complex strategies will be able to price stock-option complex strategies in more precise increments.[38]

The Exchange does not believe that the proposed rule change will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that its proposal may benefit inter-market competition as other competing option exchanges offer similar price precision for stock-option complex strategies.[39]

Additionally, the non-substantive changes proposed by the Exchange will have no impact on competition as they provide additional clarity and detail in the Exchange's rules and are not changes made for any competitive purpose.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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) of the Act and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[40] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[41] 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. The Exchange states that other options exchanges currently allow bids and offers for stock-option orders to be expressed in any decimal price the exchange determines and that waiver of the operative delay will benefit investors by immediately providing them with an additional venue that offers sub-penny pricing for stock-option orders. The Exchange further states that its proposal does not introduce new regulatory issues. The Commission finds that waiving the operative delay is consistent with the protection of investors and the public interest because other options exchanges currently allow market participants to express bids and offers for stock-option orders in any decimal price the exchange determines,[42] and waiver of the operative delay will immediately provide investors with an additional venue that allows them to express bids and offers for stock-option orders in this manner. As discussed above, the Exchange believes that the proposal will permit more precise and accurate pricing of stock-option complex strategies, which could provide investors with additional execution

[35] *See id.*

[36] See Exchange Rule 518(b)(2)(d).

[37] See Exchange Rule 515(h)(3).

[38] The Exchange notes that an updated FIX Order Interface Specification was published on 11/12/2021 to apprise Members of the change in pricing increments from $0.01 to $0.0001 for stock-option orders. *See* MIAX Options, Options Order Management using FIX Protocol, FIX Interface Specification, version: 2.5a (11/2/2021) available at *https://www.miaxoptions.com/sites/default/files/page-files/FIX_Order_Interface_FOI_v2.5a.pdf.*

[39] *See* CboeEDGX Exchange Rule 21.20(f)(1)(B) which provides that Users may express bids and offers for a stock-option order (including a QCC with Stock Order) in any decimal price the Exchange determines. The option leg(s) of a stock-option order may be executed in $0.01 increments, regardless of minimum increments otherwise applicable to the option leg(s), and the stock leg of a stock-option order may be executed in any decimal price permitted in the equity market; and Cboe Exchange Rule 5.33(f)(1)(B) which similarly provides that Users may express bids and offers for a stock-option order (including a QCC with Stock Order) in any decimal price the Exchange determines. The minimum increment for the option leg(s) of a stock-option order is $0.01 or greater, which the Exchange may determine on a class-by-class basis, regardless of the minimum increments otherwise applicable to the option leg(s), and the stock leg of a stock-option order may be executed in any decimal price permitted in the equity market. *See also* Tradedesk Updates, Cboe Options Exchange Announces Support for QCC with an Equity Leg and Improved Pricing Precision on Complex Orders with an Equity Leg (March 2, 2018) (allowing a price with four decimal places on all complex orders that include a stock leg and that are routed for electronic trading) available at *https://cdn.cboe.com/resources/release_notes/2018/QCC-w-equity-leg-and-CPS-4-digit-decimal.pdf.*

[40] 17 CFR 240.19b–4(f)(6).

[41] 17 CFR 240.19b–4(f)(6)(iii).

[42] *See supra* note 3.

opportunities. The Commission notes that although the proposal will allow bids and offers for stock-option orders to be expressed in any decimal price the Exchange determines, the option component(s) of such an order will continue to be executed in $0.01 increments. In addition, the Exchange's rules will continue to protect Priority Customer interest by providing, among other things, that if any component of a complex strategy would be executed at a price that is equal to a Priority Customer bid or offer on the Simple Book, at least one other option component of the complex strategy must trade at a price that is better than the corresponding MBBO.[43] The proposal also protects investors by codifying in the Exchange's rules that a member that submits a cQCC order to the Exchange (with or without the stock component) represents that the order satisfies the requirements of a qualified contingent trade and agrees to provide information to the Exchange related to the execution of the stock component of the order. For these reasons, the Commission designates the proposal operative upon filing.[44]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2022–17.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2022–17. 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–MIAX–2022–17, and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09853 Filed 5–6–22; 8:45 am]

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[43] *See* proposed Exchange Rule 518(c)(1)(iii). *See also* proposed Exchange Rule 518(c)(1)(iv) (stating that a complex order will not be executed at a net price that would cause any option component of the complex strategy to be executed: (A) At a price of zero; or (B) ahead of a Priority Customer order on the Simple Order Book without improving the MBBO of at least one option component of the complex strategy).

[44] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[45] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 87 FR 26251, May 3, 2022.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, May 5, 2022 at 2:00 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Thursday, May 5, 2022 at 2:00 p.m., has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b.)

Dated: May 5, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–10020 Filed 5–5–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–61, OMB Control No. 3235–0073]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:
Form S–3

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget request for extension of the previously approved collection of information discussed below.

Form S–3 (17 CFR 239.13) is used by issuers to register securities pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). Form S–3 provides investors with material information to make investment decisions regarding securities offered to the public. Form S–3 takes approximately 466.4566 hours per response and is filed by approximately 1,651 issuers annually. We estimate that 25% of the 466.4566 hours per response (116.6141 hours) is prepared by the issuer for a total annual reporting burden of 192,530 hours (116.6141 hours per response × 1,651 responses).

An agency may conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular

information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by June 8, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: May 3, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09844 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94840; File No. SR–NYSEAMER–2022–19]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of Proposed Rule Change To Modify Rule 7.31E To Add Subparagraph (f)(4) Regarding Directed Orders

May 3, 2022.

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 April 20, 2022, NYSE American LLC (''NYSE American'' 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 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

The Exchange proposes to modify Rule 7.31E to add subparagraph (f)(4) regarding Directed Orders and make other conforming changes. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 modify Rule 7.31E (Orders and Modifiers) to add new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by an ATP Holder.

The Exchange proposes to add Rule 7.31E(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31E(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31E(f)(4) would also provide that a Directed Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31E(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31E(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34E(a)(2).[4]

Proposed Rule 7.31E(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC [5] or Day [6] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31E(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31E.

Proposed Rule 7.31E(f)(4)(B) would provide that a Directed Order in a security that is having its initial listing on the Exchange would be rejected if received before the IPO Auction concludes.

Proposed Rule 7.31E(f)(4)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31E(f)(4)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes a conforming change to Rule 7.19E (Pre-Trade Risk Controls). The Exchange proposes to modify Rule 7.19E(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37E(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19E(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31E(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering ATP Holders the ability to designate orders submitted to the

[4] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34E (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34E(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34E(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected. The Exchange also proposes an additional change to correct a typographical error in Rule 7.34E(c)(1), to update the reference to ''paragraphs (c)(1)(A)–(E)'' to ''paragraphs (c)(1)(A)–(F)'' to accurately reflect the number of subparagraphs under Rule 7.34E(c)(1).

[5] *See* Rule 7.31E(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[6] *See* Rule 7.31E(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage ATP Holders to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for ATP Holders by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[7] The Exchange also believes that the Directed Order would offer ATP Holders functionality akin to order types and routing options that currently exist on other equities exchanges.[8]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[9] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the second quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is 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 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 Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer ATP Holders access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering ATP Holders the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent ATP Holders are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[12]

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 purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer ATP Holders functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[13]

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

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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:

[7] *See* Rule 7.31E(f)(1). NYSE American also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31E(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE Arca Rules 7.31–E(f)(1)–(f)(3); NYSE Chicago Rules 7.31(f)(1)–(f)(3); NYSE National Rules 7.31(f)(1)–(f)(3).

[8] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[9] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See* notes 7 & 8, *supra.*

[13] *See* note 8, *supra.*

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–NYSEAMER–2022–19 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–NYSEAMER–2022–19. 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–NYSEAMER–2022–19 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09857 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94839; File No. SR–NYSE–2022–20]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Modify Rule 7.31 To Add Subparagraph (f)(1) Regarding Directed Orders

May 3, 2022.

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 April 20, 2022, 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 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

The Exchange proposes to modify Rule 7.31 to add subparagraph (f)(1) regarding Directed Orders and make other conforming changes. 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 modify Rule 7.31 (Orders and Modifiers) to designate subparagraph (f) as describing orders with specific routing instructions and to add new subparagraph (f)(1) to provide for Directed Orders. The Exchange also proposes to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by a member organization.

The Exchange proposes to rename Rule 7.31(f), which is currently designated as Reserved, to ''Orders with Specific Routing Instructions.'' The Exchange also proposes to add Rule 7.31(f)(1), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(1) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31(f)(1) would also provide that a Directed Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(1) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(1)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[4]

Proposed Rule 7.31(f)(1)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC [5] or Day [6] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to add Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected. The Exchange also proposes to update Rule 7.34(c)(1) to refer to ''paragraphs (c)(1)(A)–(E)'' to reflect the addition of subparagraph (E).

[5] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[6] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(1)(B) would provide that a Directed Order in a security to be opened in an initial public offering (''IPO'') or a Direct Listing would be rejected if received before the IPO Auction or Direct Listing Auction concludes.

Proposed Rule 7.31(f)(1)(C) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(1)(D) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes the following conforming changes to Rule 7.19 (Pre-Trade Risk Controls) and Rule 104 (Dealings and Responsibilities of DMMs):

- The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(1) would also be included for purposes of the Gross Credit Risk Limit calculation.
- The Exchange proposes to modify Rule 104(b)(6), which specifies the orders and modifiers that DMM units are not permitted to enter. The Exchange proposes to add Directed Orders to Rule 104(b)(6) as an order type that DMM units may not enter.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering member organizations the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage member organizations to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for member organizations by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges''). On the Affiliated Exchanges, a Primary Only Order is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the order book of the exchange to which it was submitted.[7] The Exchange also believes that the Directed Order would offer member organizations functionality akin to order types and routing options that currently exist on other equities exchanges.[8]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update.[9] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the second quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is 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 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 Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer member organizations access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering member organizations the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent member organizations are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel as the Affiliated Exchanges and other exchanges offer their members functionality whereby an exchange

[7] *See* NYSE American Rule 7.31–E(f)(1); NYSE Arca Rule 7.31–E(f)(1); NYSE Chicago Rule 7.31(f)(1); NYSE National Rule 7.31(f)(1). The Affiliated Exchanges also offer variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* NYSE American Rules 7.31–E(f)(2) and (f)(3); NYSE Arca Rules 7.31–E(f)(2) and (f)(3); NYSE Chicago Rules 7.31(f)(2) and (f)(3); NYSE National Rules 7.31(f)(2) and (f)(3).

[8] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

[9] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

routes orders on behalf of a member to a specified trading center without such order interacting with the Exchange's book.[12]

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 purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer its member organizations functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[13]

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

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–2022–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–NYSE–2022–20 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09856 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* notes 7 & 8, *supra.*

[13] *See* note 8, *supra.*

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94837; File No. SR–NYSECHX–2022–06]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing of Proposed Rule Change To Modify Rule 7.31 To Add Subparagraph (f)(4) Regarding Directed Orders

May 3, 2022.

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 April 20, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' 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 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

The Exchange proposes to modify Rule 7.31 to add subparagraph (f)(4) regarding Directed Orders and make other conforming changes. The proposed 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 modify Rule 7.31 (Orders and Modifiers) to add

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

new subparagraph (f)(4) to provide for Directed Orders and to make other conforming changes to its Rules in connection with the addition of this new order type on the Exchange. The Directed Order, as further defined below, would be an order sent to the Exchange to be routed directly to an alternative trading system (''ATS'') specified by a Participant.

The Exchange proposes to add Rule 7.31(f)(4), which would define a Directed Order as a Limit Order with instructions to route on arrival at its limit price to a specified ATS with which the Exchange maintains an electronic linkage. Proposed Rule 7.31(f)(4) would further provide that Directed Orders would be available for all securities eligible to trade on the Exchange. Proposed Rule 7.31(f)(4) would also provide that a Directed Order would not be assigned a working time or interact with interest on the Exchange Book. The Exchange also proposes to provide in Rule 7.31(f)(4) that the ATS to which a Directed Order is routed would be responsible for validating whether the order is eligible to be accepted, and if such ATS determines to reject the order, the order would be cancelled.

Proposed Rule 7.31(f)(4)(A) would provide that a Directed Order must be designated for the Exchange's Core Trading Session, as defined in Rule 7.34(a)(2).[4]

Proposed Rule 7.31(f)(4)(A) would further provide that a Directed Order must be designated with a Time in Force modifier of IOC[5] or Day[6] and would be routed to the specified ATS with such modifier. The Exchange proposes that a Directed Order designated IOC would be traded in whole or in part on the ATS to which it is routed after receipt of the order, and any untraded quantity would be cancelled. The Exchange proposes that a Directed Order designated Day would expire at the end of the Core Trading Session on the day it is entered. Proposed Rule 7.31(f)(1)(A) would also provide that a Directed Order may not be designated with any other modifiers defined in Rule 7.31.

Proposed Rule 7.31(f)(4)(B) would provide that, during a trading halt or pause, an incoming Directed Order would be rejected.

Proposed Rule 7.31(f)(4)(C) would provide that a request to cancel a Directed Order designated Day would be routed to the ATS to which the order was routed.

The Exchange also proposes the following conforming changes to Rule 7.19 (Pre-Trade Risk Controls) and Article 17, Rule 5 (Brokerplex).

- The Exchange proposes to modify Rule 7.19(a)(5), which sets forth the definition of Gross Credit Risk Limit and currently provides that unexecuted orders in the Exchange Book, orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included for purposes of calculating the Gross Credit Risk Limit. The Exchange proposes to modify Rule 7.19(a)(5) to specify that orders routed on arrival pursuant to Rule 7.31(f)(4) would also be included for purposes of the Gross Credit Risk Limit calculation.
- The Exchange proposes to modify Article 17, Rule 5, which describes the Brokerplex system used by Institutional Brokers (''IBs''). Specifically, the Exchange proposes to modify Rule 5(c)(1), which enumerates the order types and modifiers defined in Rule 7.31 that are not available via Brokerplex, to include Directed Orders because the order type will not be available to IBs.

The Exchange believes that the proposed rule change would facilitate additional trading opportunities by offering Participants the ability to designate orders submitted to the Exchange to be routed to an ATS of their choosing for execution. The Exchange believes the proposed change would encourage Participants to utilize the Exchange as a venue for order entry and further believes that the proposed change could create efficiencies for Participants by enabling them to send orders that they wish to route to an alternate destination through the Exchange, thereby enabling them to leverage order entry protocols and specifications already configured for their interactions with the Exchange. The Exchange notes that the Directed Order, as proposed, would operate similarly to the Primary Only Order already offered by the Exchange, which is an order that is routed directly to the primary listing market on arrival, without being assigned a working time or interacting with interest on the Exchange Book.[7] The Exchange also believes that the Directed Order would offer its Participants functionality akin to order types and routing options that currently exist on other equities exchanges.[8]

Because of the technology changes associated with this proposed rule change, the Exchange will announce the

[4] Because the Exchange proposes that Directed Orders may only be designated for the Core Trading Session, the Exchange also proposes conforming changes to Rule 7.34 (Trading Sessions). Specifically, the Exchange proposes to modify Rule 7.34(c)(1)(E) to provide that Directed Orders designated for the Early Trading Session would be rejected and Rule 7.34(c)(3)(C) to provide that Directed Orders designated for the Late Trading Session would be rejected. The Exchange also proposes an additional change to correct a typographical error in Rule 7.34(c)(1), to update the reference to ''paragraphs (c)(1)(A)–(E)'' to ''paragraphs (c)(1)(A)–(F)'' to accurately reflect the number of subparagraphs under Rule 7.34(c)(1).

[5] *See* Rule 7.31(b)(2), which provides that a Limit Order may be designated with an Immediate-or-Cancel (''IOC'') modifier.

[6] *See* Rule 7.31(b)(1), which provides that orders may be designated with a Day modifier, and that an order to buy or sell designated Day, if not traded, will expire at the end of the designated session on the day on which it was entered.

[7] *See* Rule 7.31(f)(1). NYSE Chicago also offers variations of the Primary Only Order, including the Primary Only Until 9:45 Order, which is a Limit or Inside Limit Order that, on arrival and until 9:45 a.m. Eastern Time, routes to the primary listing market, and the Primary Only Until 3:55 Order, which is a Limit or Inside Limit Order entered on the Exchange until 3:55 p.m. Eastern Time, after which time the order is cancelled on the Exchange and routed to the primary listing market. *See* Rules 7.31(f)(2) and (f)(3). The Exchange's affiliated exchanges NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges'') also offer the Primary Only Order and variations thereof. *See* NYSE American Rules 7.31E(f)(1)–(f)(3); NYSE Arca Rules 7.31–E(f)(1)–(f)(3); NYSE National Rules 7.31(f)(1)–(f)(3).

[8] *See, e.g.,* Nasdaq Stock Market LLC (''Nasdaq''), Equity 4, Equity Trading Rules, Rule 4758(a)(ix) (defining the Nasdaq Directed Order as an order designed to use a routing strategy under which the order is directed to an automated trading center other than Nasdaq, as directed by the entering party, without checking the Nasdaq Book); Cboe EDGX Exchange, Inc. (''EDGX'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGX system and is immediately routed by EDGX to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe EDGA Exchange, Inc. (''EDGA'') Rules 11.8(c)(7) (defining the Routing/Directed ISO order type as an ISO that bypasses the EDGA system and is immediately routed by EDGA to a specified away trading center for execution) and 11.11(g)(2) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed); Cboe BZX Exchange, Inc. (''BZX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BZX system and be sent to a specified away trading center); Cboe BYX Exchange, Inc. (''BYX'') Rules 11.13(b)(3)(D) (providing for the DRT routing option, in which an order is routed to an alternative trading system as instructed) and 11.13(b)(3)(F) (defining the Directed ISO routing option, under which an ISO order would bypass the BYX system and be sent to a specified away trading center). The Exchange also believes that the Directed Order would provide functionality similar to the C–LNK routing strategy formerly offered by EDGA, in which C–LNK orders bypassed EDGA's local book and routed directly to a specified Single Dealer Platform destination. *See* Securities Exchange Act Release No. 82904 (March 20, 2018), 83 FR 12995 (March 26, 2018) (SR–CboeEDGA–2018–004) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Expand an Offering Known a Cboe Connect To Provide Connectivity to Single-Dealer Platforms Connected to the Exchange's Network and To Propose a Per Share Executed Fee for Such Service).

implementation date by Trader Update.[9] Subject to effectiveness of this proposed rule change, the Exchange anticipates that the proposed change will be implemented in the second quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934,[10] in general, and furthers the objectives of Section 6(b)(5),[11] in particular, because it is 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 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 Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and promote just and equitable principles of trade because the Directed Order would offer Participants access to additional trading opportunities by permitting them to designate orders submitted to the Exchange to be routed directly to a specified ATS for execution. The Exchange further believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market by offering Participants the option to send orders that they wish to route to an alternate destination for execution through the Exchange, which would create efficiencies to the extent Participants are able to leverage existing protocols and specifications. Finally, the Exchange notes that the proposed functionality is not novel, as both the Exchange and other exchanges offer their members functionality whereby an exchange routes orders on behalf of a member to a specified trading center without such order interacting with the exchange's book.[12]

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 purposes of the Act. The Exchange believes that the proposed rules governing Directed Orders would promote competition because they would provide for an order type on the Exchange that would facilitate additional trading opportunities for market participants. The Exchange further believes that the proposed rules would allow it to offer Participants functionality similar to order types and routing options that exist on other equities exchanges, thereby enabling the Exchange to compete with such exchanges.[13]

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

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–NYSECHX–2022–06 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–NYSECHX–2022–06. 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–NYSECHX–2022–06 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09854 Filed 5–6–22; 8:45 am]

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[9] The Exchange will also provide information regarding the ATS(s) to which a Directed Order may be designated to route by Trader Update.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See* notes 7 & 8, *supra.*

[13] *See* note 8, *supra.*

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94838; File No. SR–NASDAQ–2022–017]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 to Proposed Rule Change To Modify Equity 4, Section 4120 To Add Categories of Regulatory and Operational Halts, To Reorganize the Remaining Text of the Rule, and To Make Conforming Changes to Related Rules

May 3, 2022.

On February 22, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or

''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify Equity 4, Section 4120 to add categories of regulatory and operational halts, to reorganize the remaining text of the rule, and to make conforming changes to related rules. The proposed rule change was published for comment in the **Federal Register** on March 11, 2022.[3] On April 21, 2022, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5]

On April 29, 2022, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and superseded the proposed rule change as originally filed. Amendment No. 1 is described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Equity 4, Section 4120 to add categories of regulatory and operational halts and to reorganize the remaining text of the rule, and to make conforming changes to related rules.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* 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 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

In conjunction with adoption of an amended Nasdaq UTP Plan proposed by its participants (''Amended Nasdaq UTP Plan''),[6] Nasdaq is amending Rule 4120[7] to integrate several definitions and concepts from the Amended Nasdaq UTP Plan and to reorganize the rule in light of Nasdaq's experience with applying the rule over fifteen years as a national securities exchange. Nasdaq proposes to reorganize and amend Rule 4120 entitled Limit Up-Limit Down Plan and Trading Halts. The rule sets forth Nasdaq's authority to halt trading under various circumstances. The Exchange is a participant of the transaction reporting plan governing Tape C Securities (''Nasdaq UTP Plan'').[8] As part of these changes, Nasdaq will add categories of regulatory and operational halts, improve the rule's clarity, adopt defined terms from the Amended Nasdaq UTP Plan and delete parts of the rule that are no longer needed. Last, Nasdaq is updating cross references in other rules that are affected by the proposed changes.

Background

The Exchange has been working with other SROs to establish common criteria and procedures for halting and resuming trading in equity securities in the event of regulatory or operational issues. These common standards are designed to ensure that events which might impact multiple exchanges are handled in a consistent manner that is transparent. The Exchange believes that implementation of these common standards will assist the SROs in maintaining fair and orderly markets. Notwithstanding the development of these common standards, Nasdaq will retain discretion in certain instances as to whether and how to handle halts, as is discussed below.

Every U.S.-listed equity security has its primary listing on a specific stock exchange that is responsible for a number of regulatory functions.[9] These include confirming that the security continues to meet the exchange's listing standards, monitoring trading in that security and taking action to halt trading in the security when necessary to protect investors and to ensure a fair and orderly market. While these core responsibilities remain with the primary listing venue, trading in the security can occur on multiple exchanges that have unlisted trading privileges for the security[10] or in the over-the-counter market, regulated by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The exchanges and FINRA are responsible for monitoring activity on the markets over which they have oversight, but also must abide by the regulatory decisions made by the Primary Listing Market. For example, a venue trading a security pursuant to unlisted trading privileges must halt trading in that security during a Regulatory Halt, which is a defined term under the proposed rules,[11] and may only trade the security once the Primary Listing Market has cleared the security to resume trading.

All SROs have rules that require them to honor a Regulatory Halt. Nasdaq, as a Primary Listing Market, also has rules

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94370 (March 7, 2022), 87 FR 14071.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 94778, 87 FR 25069 (April 27, 2022). The Commission designated June 9, 2022 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] On February 11, 2021, the Nasdaq UTP Plan participants filed Amendment 50 to the Plan, to revise provisions governing regulatory and operational halts. *See* Letter from Robert Brooks, Chairman, UTP Operating Committee, Nasdaq UTP Plan, to Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2021. The Nasdaq UTP Plan subsequently filed two partial amendments to the 50th Amendment, on March 31, 2021 and on April 7, 2021. The SEC approved the amendments on May 28, 2021. *See* Securities Exchange Act Release No. 34–92071 (May 28, 2021), 86 FR 29846 (June 3, 2021) (S7–24–89). The Amended Nasdaq UTP Plan includes provisions requiring participant self-regulatory organizations (''SROs'') to honor a Regulatory Halt declared by the Primary Listing Market. The provisions in the Nasdaq UTP Plan, and the plan for consolidation of data for non-Nasdaq-listed securities, the Consolidated Tape System and Consolidated Quotations System (collectively, the ''CTA/CQS Plan''), include provisions similar to the changes proposed by the Exchange in this filing.

[7] References herein to Nasdaq Rules in the 4000 Series shall mean Rules in Nasdaq Equity 4.

[8] Each transaction reporting plan has a securities information processor (''SIP'') responsible for consolidation of information for the plan's securities, pursuant to Rule 603 of Regulation NMS. The transaction reporting plan for Nasdaq-listed securities is known as The Joint Self-Regulatory Organization Plan Governing The Collection, Consolidation and Dissemination of Quotation and Transaction Information For Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis or the ''Nasdaq UTP Plan.'' Pursuant to the Nasdaq UTP Plan, the UTP SIP, which is Nasdaq, consolidates order and trade data from all markets trading Nasdaq-listed securities. The Exchange uses the term ''UTP SIP'' herein when referring specifically to the SIP responsible for consolidation of information in Nasdaq-listed securities.

[9] Nasdaq is proposing to adopt Primary Listing Market as a new term, defined in Nasdaq UTP Plan, Section X.A.8, as follows: ''[T]he national securities exchange on which an Eligible Security is listed. If an Eligible Security is listed on more than one national securities exchange, Primary Listing Market means the exchange on which the security has been listed the longest.''

[10] In addition, securities may also be listed on the New York Stock Exchange (''dually-listed''). *See* Rules 5005(a)(11), 5220 and IM–5220.

[11] *See* proposed Rule 4120(a)(11).

outlining the circumstances in which it will halt trading in its listed securities, including situations in which such halts are for regulatory purposes [12]—and therefore are applicable to all markets trading the security—or for operational purposes, which would not halt trading on other markets. However, the trading halt rules are not consistent across SROs. Consequently, events that might constitute a Regulatory Halt for securities listed on one Primary Listing Market theoretically might not be grounds for a Regulatory Halt in securities listed on another Primary Listing Market. Such inconsistency among exchange rules could lead to confusion in circumstances such as a cross market event, which could be deemed ''Extraordinary Market Activity.'' [13]

While the existing rule generally has worked as intended to afford the Exchange authority to initiate a Regulatory Halt in appropriate cases, Nasdaq's experience is that the current rule may not contemplate some situations where a Regulatory Halt would help to maintain fair and orderly markets. For example, the current definition of ''Extraordinary Market Activity'' focuses on events where trading occurs significantly away from pre-event market prices. However, there may be other situations where trading proceeds in an orderly fashion despite a computer error that causes duplicative orders, bad data or other erroneous information that could impact investors' understanding of the market or their trading activity. The Exchange believes it would facilitate fair and orderly markets to give Primary Listing Markets greater flexibility to consider the facts and circumstances of each case and decide whether a Regulatory Halt is appropriate.

The complex and interconnected market structure in the United States also relies on consolidated market data processed and disseminated by the SIPs. In certain circumstances, the loss of this information or issues with the accuracy or timeliness of the information might cause a Primary Listing Market to determine that a trading halt is appropriate. The Exchange believes that further guidance in the rules will assist market participants in better understanding how various scenarios would be handled.

The Exchange believes that the cross-market proposed changes would address these concerns by: (1) Adopting uniform rules regarding the trigger points for regulatory trading halts in situations most likely to have an impact across markets and multiple listing venues; (2) addressing more scenarios in the uniform rule where a Primary Listing Market may need to implement a Regulatory Halt to maintain fair and orderly markets; and (3) adding provisions that apply to SIP-related issues to increase transparency into how these situations would be handled.

As noted above, the proposed changes that would be uniformly applied across SROs are those that relate to cross-market events as set forth in the Amended Nasdaq UTP Plan. However, there will still be situations where personnel at the Primary Listing Market will need to determine the impact of the cross-market event on the securities listed on its market and use discretion in deciding whether to halt trading in some or all securities during a cross-market event that affects securities listed on different markets. In making a determination as to whether to declare a Regulatory Halt for Extraordinary Market Activity, the Primary Listing Market will consider the totality of information available concerning the severity of the issue, its likely duration, potential impact on members and other market participants, and it will make a good-faith determination that the criteria for declaring a Regulatory Halt have been satisfied and that a Regulatory Halt is appropriate.[14] Moreover, the Primary Listing Market will consult, if feasible, with the affected Trading Center(s), other Plan Participants, or the Processor, as applicable, regarding the scope of the issue and what steps are being taken to address the issue. Exchanges may also declare a Regulatory Halt when it determines that it is necessary to maintain a fair and orderly market.[15]

While the Exchange and the other SROs intend to harmonize certain aspects of their trading halt rules, other elements of the rules will continue to be unique to each market. The Exchange believes that this is appropriate to reflect different products listed or traded on each market and the unique relationship of the Primary Listing Market to its listed companies. It is anticipated that these unique rules would most likely be invoked in cases where the Primary Listing Market's decision on whether to institute a Regulatory Halt turns on specific information related to an individual security or issuer, such as the dissemination of news and the issuer's ability to meet listing standards, rather than broader market issues stemming from Extraordinary Market Activity or loss of consolidated market data from a SIP.

In addition to the changes noted above, the Exchange is deleting provisions that are no longer needed and reorganizing the rule to improve its clarity. The Exchange is also making a handful of non-substantive changes to rule text to improve its clarity. The Exchange will implement all of the changes proposed herein in conjunction with other SROs implementing the necessary rule changes. The Exchange will publish an Equity Trader alert at least 30 business days prior to implementing the proposed changes.

Definitions

The Exchange proposes adding a definitions section as Rule 4120(a) to consolidate the various definitions that will be used in the Rule, some of which are taken from the Amended Nasdaq UTP Plan. Nasdaq is adopting the following terms from the Amended Nasdaq UTP Plan: ''Extraordinary Market Activity,'' ''Material SIP Latency,'' ''Operating Committee,'' ''Operational Halt,'' ''Primary Listing

[12] Nasdaq's current Rule 4120 establishes a limited number of reasons for instituting a Regulatory Halt for a Nasdaq-listed security. These reasons are: To permit the dissemination of material news concerning a listed company (Rule 4120(a)(1)); with respect to an American Depository Receipt (''ADR'') listed on Nasdaq, where another U.S. or foreign exchange that lists the security or the security underlying the ADR imposes a Regulatory Halt on the security listed on its market (Rule 4120(a)(4)); where Nasdaq requests information from the issuer relating to material news, the issuer's ability to meet Nasdaq's listing standards, or to protect investors (Rule 4120(a)(5)); in the event that extraordinary market activity in the security is occurring, ''such as the execution of a series of transactions for a significant dollar value at prices substantially unrelated to the current market for the security'' that is ''likely to have a material effect on the market for the security'' and the Exchange believes it is ''caused by the misuse or malfunction of an electronic quotation, communication, reporting or execution system operated by, or linked to,'' Nasdaq or another market (Rule 4120(a)(6)); in the event of an initial public offering (''IPO'') (Rule 4120(a)(7)); with respect to an index warrant, under certain specified conditions, or when appropriate in the interests of a fair and orderly market (Rule 4120(a)(8)); with respect to certain ''Derivative Securities Products'' (defined in Rule 4120(b)(4)(A)) when certain pricing information concerning the instrument is not available or is not being disseminated to all market participants at the same time (Rules 4120(a)(9) and (10)); for securities not covered by the Limit Up-Limit Down Plan, in the event a single stock trading pause is triggered (Rule 4120(a)(11)); and for securities covered by the Limit Up-Limit Down Plan, in the event of a trading pause (Rule 4120(a)(12)).

[13] The proposed definition of Extraordinary Market Activity encompasses a market event that affects multiple markets. *See* proposed Rule 4120(a)(2) (incorporating by reference Nasdaq UTP Plan, Section X.A.1. Thus, such cross-market events could be considered Extraordinary Market Activity.

[14] The Exchange will consider these factors for all Regulatory Halts, not simply those caused by Extraordinary Market Activity.

[15] *See* proposed Rule 4120(a)(11) and Amended Nasdaq UTP Plan, Section X.A.10.

Market,'' ''Processor,'' [16] ''Regulatory Halt,'' ''Regular Trading Hours,'' [17] ''SIP Halt,'' ''SIP Halt Resume Time,'' and ''SIP Outage.'' The definitions of ''Derivatives Securities Product,'' ''IPO,'' ''Pre-Market Session'' and ''Required Value'' have been moved into the definitions section from elsewhere in the current rule without change. The definition of ''Post-Market Session'' has been moved from elsewhere in the rule with a minor change deleting the alternative closing time of 4:15 p.m. as all securities traded on Nasdaq commence their closing cross process at 4:00 p.m.[18]

First, the Exchange proposes to add the definition of ''Primary Listing Market'' [19] to Rule 4120, which will have the same meaning as in the Amended Nasdaq UTP Plan, Section X.A.8. As is currently the case under Rule 4120 and under the Nasdaq UTP Plan, all Regulatory Halt decisions are made by the market on which the security has its primary listing. This reflects the regulatory responsibility that the Primary Listing Market has for fair and orderly trading in the securities that list on its market and its direct access to its listed companies, which are required to advise it of certain events and maintain lines of communication with the Primary Listing Market. The proposed definition makes clear that if a security is listed on more than one market (a dually-listed security), the Primary Listing Market means the exchange on which the security has been listed the longest. This provision matches language used in the definition of ''Primary Listing Exchange'' in the Limit-Up Limit-Down Plan and will avoid conflict in the event of dually-listed securities.

Second, the Exchange proposes to replace the definition of ''Extraordinary Market Activity'' with a broader definition of the term taken from Section X.A.1. of the Amended Nasdaq UTP Plan.[20] The current rule establishes a three-part test for Extraordinary Market Activity:

(1) Extraordinary Market Activity must be occurring in the security—the sole example of such activity included in the rule is ''the execution of a series of transactions for a significant dollar value at prices substantially unrelated to the current market for the security, as measured by the national best bid and offer,'' and

(2) The Exchange must determine that such Extraordinary Market Activity is likely to have a material effect on the market for the security, and

(3) The Exchange believes that either: (i) Such activity is caused by the misuse or malfunction of an electronic quotation, communication, reporting or execution system operated by, or linked to, the Exchange; (ii) after consultation with another national securities exchange trading the security on an unlisted trading privileges basis, that such activity is caused by the misuse or malfunction of an electronic quotation, communication, reporting or execution system operated by, or linked to, such other national securities exchange; or (iii) after consultation with FINRA regarding a FINRA facility trading the security, such activity is caused by the misuse or malfunction of such FINRA facility or an electronic quotation, communication, reporting, or execution system linked to such FINRA facility.

Although the single scenario in element (1) of the test is not exclusive, the Exchange believes that market participants would benefit from the inclusion of other scenarios that might constitute ''Extraordinary Market Activity.'' For example, experience indicates that significant market events do not always result in price dislocation. In some cases, trading may remain orderly. Moreover, price discovery—at least when measured by the absence of large price changes—may appear to be orderly, but in fact there may be confusion or information missing (*e.g.,* quote or transaction information) that is important to participants. The absence of accurate information could make it difficult for market participants to properly confirm the positions they own, the impact of the event, or the correct prices for securities.

The proposed definition of Extraordinary Market Activity is the same definition in Section X.A.1. of the Amended Nasdaq UTP Plan.[21] The new definition updates and consolidates the terminology and broadens applicability of the term in comparison to the current definition, by making it clear that Extraordinary Market Activity may occur solely on the Exchange or multiple markets, referred to as ''Trading Centers'' in the proposed rule change. A ''Trading Center,'' which is defined in Rule 600(b)(95) of Regulation NMS, refers to a ''national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent.'' The Amended Nasdaq UTP Plan definition of Extraordinary Market Activity also explicitly refers to disruptions or malfunctions at a SIP or a member of a Trading Center, whereas the current rule, as discussed above, does not. To qualify as Extraordinary Market Activity, the event must have a ''severe and continuing negative impact'' on a market-wide basis on quoting, order, or trading activity or the availability of market information necessary to maintain a fair and orderly market.

The new definition of Extraordinary Market Activity also explains what constitutes a ''severe and continuing negative impact.'' In addition to the scenario in the current rule involving significant price movement, the proposed change adds two new scenarios to provide additional transparency to member firms:

- Duplicative or erroneous quoting, order trade reporting, or other related message traffic between one or more Trading Centers or their members; and
- The unavailability of quoting, order or transaction information, or regulatory messages, for a sustained period.

These problems may cause market participants to change their trading behavior or withdraw from the market

[16] The Exchange proposes to also define the term ''SIP'' to have the same meaning as the term ''Processor'' as set forth in the Amended Nasdaq UTP Plan. Because the terms ''Processor'' and ''SIP'' are also used throughout the Rules, at times, to apply to processors of information furnished pursuant to the Consolidated Tape Association Plan (''CTA Plan''), the term ''Processor'' may, in those applicable circumstances, refer to the processor of transactions in Tape A and B securities, as set forth in the CTA Plan.

[17] The Exchange notes that pursuant to existing Rule 4120(b)(4), the Regular Market Session occurs until 4:00 p.m. or 4:15 p.m., and the Post-Market Session begins at 4:00 p.m. or 4:15 p.m.

[18] As noted above, the Exchange is adopting several new terms that have the same meaning as those terms are defined in the Amended Nasdaq UTP Plan. Each of the national market system plans governing the single plan processors has identical definitions of these terms, thus there will be uniformity in the meaning of the terms among such plans as well as among the rules of the SROs.

[19] *See* proposed Rule 4120(a)(9).

[20] *See* proposed Rule 4120(a)(2).

[21] ''Extraordinary Market Activity'' means a disruption or malfunction of any electronic quotation, communication, reporting, or execution system operated by, or linked to, the Processor or a Trading Center or a member of such Trading Center that has a severe and continuing negative impact, on a market-wide basis, on quoting, order, or trading activity or on the availability of market information necessary to maintain a fair and orderly market. For purposes of this definition, a severe and continuing negative impact on quoting, order, or trading activity includes (i) a series of quotes, orders, or transactions at prices substantially unrelated to the current market for the security or securities; (ii) duplicative or erroneous quoting, order, trade reporting, or other related message traffic between one or more Trading Centers or their members; or (iii) the unavailability of quoting, order, or transaction information for a sustained period.

entirely. When serious enough, this can affect the fair and orderly operation of the market. In determining whether to initiate a trading halt, Nasdaq would, as set forth in the Amended Nasdaq UTP Plan and in proposed Rule 4120(b)(2)(D), consider the totality of information available concerning the severity of the issue, its likely duration, potential impact on members and other market participants, and will make a good-faith determination that the criteria for declaring a Regulatory Halt has been satisfied and that a Regulatory Halt is appropriate. Therefore, the Exchange, acting as the Primary Listing Market, in consultation with the affected trading centers, other SIP Plan participants, or the Processor, as applicable, where feasible, will retain discretion to evaluate the magnitude of each situation to determine whether the event meets the definition of Extraordinary Market Activity.

As with the current rule, the three scenarios included by reference in the new definition would not be exhaustive. This enables the Primary Listing Market to act in the best interests of the market when confronted with unexpected events. However, the Exchange believes that the three scenarios included in the rule cover many of the most likely events that may occur. As is currently the case, the Exchange anticipates providing public notice of Extraordinary Market Activity as soon as it is practicable, with updates as necessary, to assist firms in monitoring the status of issues. These notices, coupled with the proposed rule, will assist participants by alerting them to the situations most likely to result in trading halts.

The third set of new proposed definitions would be specific to events involving the SIP. While Nasdaq recognizes that many events involving the SIP would also meet the definition of ''Extraordinary Market Activity,'' the Exchange believes that the critical role of the SIPs in market infrastructure factors in favor of additional guidance on how such events will be handled. The definitions of ''SIP Outage,'' ''Material SIP Latency,'' ''SIP Halt Resume Time,'' and ''SIP Halt'' are intended to provide additional guidance and specific processes to address this subset of potential market issues. In addition, the Exchange is proposing to define terms related to SIP governance needed in order to understand these definitions:

• ''Processor'' or ''SIP'' [22] have the same meaning as the term ''Processor'' set forth in the Nasdaq UTP Plan, namely the entity selected by the Participants to perform the processing functions set forth in the Plan. Because the terms ''Processor'' and ''SIP'' are also used throughout the Rules, at times, to apply to processors of information furnished pursuant to the CTA Plan, the term ''Processor'' and ''SIP'' may, in those applicable circumstances, refer to the processor of transactions in Tape A and B securities, as set forth in the CTA Plan.

• ''SIP Plan'' [23] is defined as the Nasdaq UTP Plan.

• ''Operating Committee'' [24] is defined as having the same meaning as in the Nasdaq UTP Plan, namely the committee charged with administering the Nasdaq UTP Plan.

The Exchange is proposing to adopt a category of Regulatory Halt, called a ''SIP Halt,'' [25] which will have the same meaning as that term is defined in Section X.A.11. of the Nasdaq UTP Plan, namely ''a Regulatory Halt to trading in one or more securities that a Primary Listing Market declares in the event of a SIP Outage or Material SIP Latency.'' This new category of Regulatory Halt will address situations where the Primary Listing Market declares a Regulatory Halt in one or more securities as a result of a SIP Outage or Material SIP Latency (each is discussed below). While a SIP Halt may be declared in a single stock, Nasdaq anticipates that most events will impact multiple securities or even all securities with their primary listing on a particular market. Because of the complexities inherent in these types of halts, the Exchange is proposing special procedures for the halting and resuming of trading as a result of a SIP Halt. These are discussed in more detail later.

The Exchange is proposing to define a ''SIP Outage'' [26] as having the same meaning as in Section X.A.13 of the Amended Nasdaq UTP Plan. Specifically, the Exchange is proposing to define SIP Outage to mean a situation in which the Processor has ceased, or anticipates being unable, to provide updated and/or accurate quotation or last sale price information in one or more securities for a material period that exceeds the time thresholds for an orderly failover to backup facilities established by mutual agreement among the Processor, the Primary Listing Market for the affected securities, and the Operating Committee unless the Primary Listing Market, in consultation with the Processor and the Operating Committee, determines that resumption of accurate data is expected in the near future.

Recent experience with events involving a loss of consolidated data from the SIP has shown that in many cases, the least disruptive outcome in the event of a brief interruption in data is to not halt trading in the affected securities if the market is fair and orderly. For example, in August 2013, Nasdaq halted trading in Nasdaq-listed securities due to an interruption in UTP SIP data due to uncertainty about the impact the loss of data would have on market participants. Although the UTP SIP successfully restarted the system within its primary data center and was operational within 17 minutes, the market remained halted for 3 hours at the request of market participants so that they could manage their books, clear stale orders and reconnect to the system. By contrast, the New York Stock Exchange (''NYSE''), benefitting from this prior experience, did not halt trading during a loss of CTA/CQS data in October 2014 and failed over to back-up facilities within 30 minutes of the loss of SIP data. Because NYSE did not halt trading, firms did not need to reconnect and clear order books. As a result, the duration of the NYSE event—measured from loss of SIP data to end of the issue—was shorter and caused less disruption to the market even though the scope of the underlying problem that caused the loss of data from both SIPs was comparable.

At the direction of the Operating Committees, each processor has invested significant money and effort into improving the resiliency of the SIPs. This will increase the likelihood that SIPs will failover rapidly and commence disseminating valid data. Of course, there could still be situations where the failover does not work as expected, or the problem is not cured despite the redundancy available in the backup center. It is in these situations that the Exchange and the other SROs believe that the need for a SIP Halt is most likely to arise.

For this reason, the proposed definition focuses on the agreed time frames for an orderly failover. Emergency procedures applicable to the Processor provide that when a determination is made to failover to the secondary data center, the Processor shall endeavor to complete the failover within 10 minutes.[27]

Accordingly, the Primary Listing Market would be expected to consider a SIP Halt in the event of the loss of SIP

[22] *See* proposed Rule 4120(a)(10).

[23] *See* proposed Rule 4120(a)(17).

[24] *See* proposed Rule 4120(a)(5).

[25] *See* proposed Rule 4120(a)(14).

[26] *See* proposed Rule 4120(a)(16).

[27] *See https://www.utpplan.com/DOC/UTP_SIP_Emergency_Procedures.pdf.*

data once the loss in data extends or is anticipated to extend for a material period that exceeds the same agreed-upon 10 minute failover thresholds, unless the Primary Listing Market, in consultation with the Processor and the responsible Operating Committee, determines that resumption of accurate data is expected in the near future. The Exchange, in consultation with the other SROs, considered and rejected specifying a numerical time limit after which a SIP Halt would be required. Because of the significant impact a broad trading halt can have on market confidence, the Exchange believes Primary Listing Markets should retain discretion to consider the facts of the incident in evaluating a SIP Halt to avoid having to halt trading despite knowing that the SIP is about to resume data dissemination. Instead, the Primary Listing Market, in consultation with other SROs, SIPs and market participants where feasible, would continually re-evaluate whether a SIP Halt is appropriate and take action when, in its judgment, the thresholds in the definition have been passed. The Primary Listing Market retains discretion throughout the process to institute a Regulatory Halt in good faith—even within the 10 minute failover window—if trading appears disorderly, price discovery has been impacted, or it is otherwise in the interests of a fair and orderly market to halt trading.

In addition to situations where a SIP is no longer disseminating data, circumstances may arise where quotation or last sale price information from the SIP is delayed or stale due to a significant increase in latency. Minor latency in the data will always exist given the nature of a consolidated feed, where data from multiple markets is validated, normalized, consolidated and then distributed. However, significant latency can impact trading decisions and market confidence if participants are unsure whether data accurately reflects the current state of the market.

The Exchange is proposing to define ''Material SIP Latency'' [28] as having the same meaning as in Section X.A.5 of the Amended Nasdaq UTP Plan. Specifically, the Exchange is proposing to define Material SIP Latency to mean a delay of quotation or last sale price information in one or more securities between the time data is received by the Processor and the time the Processor disseminates the data over the Processor's vendor lines, which delay the Primary Listing Market determines, in consultation with, and in accordance with, publicly disclosed guidelines established by the Operating Committee, to be (a) material and (b) unlikely to be resolved in the near future. In this regard, SIP Emergency procedures presently state that ''SIP material latency refers to sustained latency of 100 milliseconds or greater for 10 minutes caused by a technical issue at the Processor.'' [29] The Emergency Procedures have various escalation points to advise the Primary Listing Market, the Operating Committee, and market participants. Under the proposal, the Primary Listing Market, in consultation with the Operating Committee, would be responsible for determining when this latency has become a Material SIP Latency.

Because guidelines are designed as an early warning system to mobilize decision makers, many latency events that exceed the thresholds in the guidelines would not constitute Material SIP Latency resulting in a SIP Halt. Instead, the Primary Listing Market, in consultation with the Operating Committee, would be expected to evaluate the severity of the latency and its continued duration and consider whether the issue is likely to be resolved in the near future. As in the case of a SIP Outage, the Exchange, in consultation with other SROs, considered adopting fixed latency metrics in the rule, but for several reasons, it determined that this would be counterproductive. First, it could create situations where a SIP Halt is imposed even where resolution is imminent. Second, greater flexibility will enable the Exchange and other Primary Listing Markets to learn from experience about how various levels of latency affect trading. Fixed thresholds in the rule might also become outdated over time if latency levels drop due to system enhancements. Regardless of the thresholds, the Primary Listing Market always retains the authority to institute a Regulatory Halt if it determines, in good faith, a halt to be in the interests of a fair and orderly market.

The Exchange proposes to add a definition of ''Regulatory Halt'' [30] as having the same meaning as in Section X.A.10 of the Amended Nasdaq UTP Plan. Specifically, the Exchange has proposed to define Regulatory Halt to mean a halt declared by the Primary Listing Market in trading in one or more securities on all Trading Centers for regulatory purposes, including for the dissemination of material news, news pending, suspensions, or where otherwise necessary to maintain a fair and orderly market.[31] A Regulatory Halt includes a trading pause triggered by Limit Up-Limit Down, a halt based on Extraordinary Market Activity, a trading halt triggered by a Market-Wide Circuit Breaker, and a SIP Halt. The new term Regulatory Halt consolidates the various reasons for such a halt that are enumerated in the proposed Rule 4120(b). In addition to the specific reasons, the rule would memorialize the Primary Listing Market's ability to implement a Regulatory Halt where otherwise necessary to preserve a fair and orderly market.[32] The definition also makes clear that market-wide circuit breakers, codified in Rule 4121, constitute a Regulatory Halt. These circuit breakers provide for coordinated cross-market trading halts designed to stop trading temporarily or, under extreme circumstances, close the markets before the normal close of the trading session.

Finally, the Exchange proposes to add a definition of ''Operational Halt,'' [33] which is defined as having the same meaning as in Section X.A.7 of the Amended Nasdaq UTP Plan. Specifically, the Exchange is proposing to define Operational Halt to mean a halt in trading in one or more securities only on the market declaring the halt. An Operational Halt is effective only on Nasdaq; other markets are not required to halt trading in the impacted securities. In practice, the Exchange has always had the capacity to implement operational halts in specified circumstances.[34] The proposed change would provide greater clarity on when an Operational Halt may be implemented and the process for halting and resuming trading in the event of an

[28] *See* proposed Rule 4120(a)(4).

[29] *See https://www.utpplan.com/DOC/UTP_SIP_Emergency_Procedures.pdf.*

[30] *See* proposed Rule 4120(a)(11).

[31] The Exchange's authority to declare a Regulatory Halt to maintain a fair and orderly market is explicitly included in the definition of Regulatory Halt. The Exchange will institute a Regulatory Halt if it makes a determination that it is necessary to maintain a fair and orderly market. The Exchange believes that the addition of this basis to declare a Regulatory Halt will protect investors by giving the Exchange explicit authority to act in unforeseen situations not covered by other provisions of Rule 4120.

[32] As provided for in the Nasdaq UTP Plan, the Proposed Rule would permit the Exchange to declare a Regulatory Halt for a security for which it is the Primary Listing Market, in the event of national, regional, or localized disruption that necessitates a Regulatory Halt to maintain a fair and orderly market.

[33] *See* proposed Rule 4120(a)(6).

[34] *See* By-Laws of the Nasdaq Stock Market LLC, Section 5 (''Authority to Take Action Under Emergency or Extraordinary Market Conditions''), available at *https://listingcenter.nasdaq.com/assets/rulebook/nasdaq/rules/NASDAQ_Corporate_Organization_Nasdaq_LLC.pdf.*

Operational Halt. An Operational Halt is not a Regulatory Halt.[35]

Regulatory Halt Types

The Exchange proposes to consolidate the various types of situations that form the basis for declaring a Regulatory Halt in Rule 4120(b). The proposed rule change would divide the situations that form the basis of the Exchange's authority to declare a Regulatory Halt in a security for which the Exchange is the Primary Listing Market into three categories: (1) As provided by the SIP Plans; (2) discretionary Regulatory Halts; and (3) mandatory Regulatory Halts.

The first category concerns situations enumerated in the SIP Plan, specifically related to a SIP Outage, Material SIP Latency, or Extraordinary Market Activity.

The second category provides the Exchange with discretion to declare a Regulatory Halt in situations described by the proposed rule, such as when the Exchange requests certain information from an issuer and for a security subject to an IPO. The Exchange believes that discretion in determining whether to impose a Regulatory Halt is appropriate because of the many facts and circumstances that must be considered by the Primary Listing Market in determining whether to halt trading. A rule establishing exact standards for a mandatory halt would risk forcing the Exchange to halt trading in circumstances where other facts may weigh against a halt, thereby forcing the Exchange to act in a way that is not in the best interests of the market. Alternatively, fixed standards could also prevent the Exchange from halting in circumstances where a Regulatory Halt would be appropriate. Instead, the proposed change would outline the types of scenarios where the Primary Listing Market may initiate a Regulatory Halt after consulting with the entities specified in the Amended Nasdaq UTP Plan, where feasible. However, there may be situations where such consultation may not be possible due to technical issues or time sensitivity. The proposed change would preserve the Exchange's ability to act in the best interests of the market in these circumstances, consistent with the Amended Nasdaq UTP Plan.

As under the current rule, the proposed change continues to allow the Exchange to institute a Regulatory Halt in circumstances where the Exchange requests additional information from an issuer (current Rule 4120(a)(5) and proposed Rule 4120(b)(1)(B)(i)),[36] to allow for the dissemination of material news (current Rule 4120(a)(1) and new Rule 4120(b)(1)(B)(ii)); to facilitate the initiation of trading of an IPO (current Rule 4120(a)(7) and proposed Rule 4120(b)(1)(B)(iii)) and to protect a fair and orderly market in the trading of index warrants (current Rule 4120(a)(8) and proposed Rule 4120(b)(1)(B)(iv)). Proposed Rule 4120(b)(1)(B)(v), codified without material change from current Rule 4120(a)(9), gives the Exchange discretion to halt a series of Portfolio Depository Receipts, Index Fund Shares (as defined in Rule 5705), Index-Linked Exchangeable Notes, Equity Gold Shares, Trust Certificates, Commodity-Based Trust Shares, Currency Trust Shares, Commodity Index Trust Shares, Commodity Futures Trust Shares, Partnership Units, and Managed Trust Securities (as defined in Rule 5711(a)–(h) and (j), respectively), or NextShares (as defined in Rule 5745) listed on Nasdaq if the Intraday Indicative Value (as defined in Rule 5705), for Portfolio Depository Receipts or Index Fund Shares, for derivative securities as defined in Rule 5711(a), (b), and (d)–(h), Rule 5711(j) for Managed Trust Securities, or Rule 5745 for NextShares) or the index value applicable to that series is not being disseminated as required, during the day in which the interruption to the dissemination of the Intraday Indicative Value or the index value occurs. It requires the Exchange to halt trading in these instruments no later than the beginning of trading on the day following the interruption to the dissemination of the Intraday Indicative Value or the index value if the interruption persists past the trading day on which it occurs. The Exchange would also retain discretionary authority to halt trading in a series of Portfolio Depository Receipts, Index Fund Shares, Exchange Traded Fund Shares (as defined in Rule 5704), Managed Fund Shares, Index-Linked Exchangeable Notes, Equity Gold Shares, Trust Certificates, Commodity-Based Trust Shares, Currency Trust Shares, Commodity Index Trust Shares, Commodity Futures Trust Shares, Partnership Units, Trust Units (as defined in Rule 5711(i)), Managed Trust Securities, Currency Warrants (as defined in Rule 5711(k)), NextShares, or Proxy Portfolio Shares (as defined in Rule 5750) based on a consideration of the following factors: (A) Trading in underlying securities comprising the index or portfolio applicable to that series has been halted in the primary market(s), (B) the extent to which trading has ceased in securities underlying the index or portfolio, or (C) the presence of other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market.

Proposed Rule 4120(b)(1)(B)(vi) gives the Exchange discretion to halt trading in an American Depository Receipt (''ADR'') or other Nasdaq-listed security when the foreign securities exchange or market listing the security underlying the ADR or the Nasdaq-listed security or the regulatory authority overseeing such foreign securities exchange or market institutes a halt for regulatory reasons. The Exchange is deleting text that presently exists in the Rule covering ADR and other Nasdaq-listed security halts, at Rule 4120(a)(4), which references national securities exchanges instituting a halt for ''regulatory reasons'' because under the proposed new rules, a Regulatory Halt will be issued by the Primary Listing Exchange. If the other national securities exchange is the primary listing exchange and declares a regulatory halt, the security will be subject to a halt by the Exchange. Thus, such a halt on the Exchange will be mandatory. The proposed amended rule will consider only actions taken by a foreign exchange that halts the Nasdaq-listed security, or security underlying an ADR, on its market for regulatory reasons (foreign exchanges do not fall within the definition of a ''primary listing market'' and therefore their regulatory halts do not fall within the Amended Nasdaq UTP Plan's definition of Regulatory Halts). The Exchange will then assess the regulatory reasons underlying the halt on the foreign market and possibly initiate a Regulatory Halt.

Proposed Rule 4120(b)(1)(B)(vii) would permit the Exchange to declare a Regulatory Halt for a security for which it is the Primary Listing Market, in the event of national, regional, or localized disruption that necessitates a Regulatory Halt to maintain a fair and orderly market. This proposal incorporates an identical provision in the Nasdaq UTP Plan.

The third category of Regulatory Halts concerns situations in which it is mandatory that the Exchange must

[35] The Exchange notes that it proposes to amend the existing definition of the term ''Post-Market Session'' to clarify that it is a trading session that begins after ''Regular Trading Hours''—a term that, in turn, is defined in the Nasdaq UTP Plan—and that such session begins at ''approximately'' 4:00 p.m. The addition of the term ''approximately'' reflects the fact that the Nasdaq Closing Cross, which precedes the Post-Market Session at 4:00 p.m., is not instantaneous. *See* Proposed Rule 4120(a)(7).

[36] As proposed, Rule 4120(b)(1)(B)(i) provides that the Exchange's determination regarding a trading halt would be made consistent with Section X.C of the Amended Nasdaq UTP Plan.

declare a Regulatory Halt. Proposed Rule 4120(b)(1)(C)(i) codifies without substantive modification the existing provisions of Rule 4120(a)(10) in situations where the Exchange becomes aware that the net asset value of a Derivative Securities Product (or the Disclosed Portfolio in the case of Managed Fund Shares, the Composition File in the case of NextShares, or in the case of Proxy Portfolio Securities, a Proxy Basket, or the Fund Portfolio) is not being disseminated to all participants at the same time. The Exchange is required to halt trading in the Derivative Securities Product when this occurs. Similarly, proposed Rule 4120(b)(1)(C)(ii) retains without substantive modification the existing rule with respect to the Limit Up-Limit Down Plan (current Rule 4120(a)(12)).[37] The Exchange proposes to make clear in Rule 4120(b)(1)(C)(iii) that a trading halt pursuant to extraordinary market volatility (market-wide circuit breakers), as is described in Rule 4121, constitutes a Regulatory Halt. Finally, the Exchange is incorporating Rule 4120(a)(13) into proposed Rule 4120(b)(1)(C)(iv). Rule 4120(a)(13) requires Nasdaq to halt trading in an Equity Investment Tracking Stock (as defined in Rule 5005) or Subscription Receipt (listed under Rule 5520) whenever Nasdaq halts or suspends trading in a security tracked by the Equity Investment Tracking Stock or the common stock into which the Subscription Receipt is exchangeable.

The Exchange is proposing to move or delete certain elements in the current list of situations that form the basis for declaring a Regulatory Halt in Rule 4120(a). First, the Exchange is deleting the current definition of Extraordinary Market Activity in Rule 4120(a)(6), which it proposes to replace with the updated and more extensive definition previously discussed. Second, the Exchange is proposing to delete current Rule 4120(a)(11), which establishes a trading pause in the event of large price moves in securities not covered by the Limit Up-Limit Down Plan.[38] As the Limit Up-Limit Down Plan is now fully implemented, this subsection is no longer necessary. In addition, the Exchange proposes moving existing Rule 4120(a)(2) and (a)(3) to proposed Rule 4120(b)(3) covering declaration of a Regulatory Halt by a Primary Listing Market other than Nasdaq. These provisions are discussed in more detail below.

Initiating a Regulatory Halt

In coordination with the other SROs, the Exchange developed proposed Rule 4120(b)(2) to provide detailed and consistent rules on how a Primary Listing Market will initiate a Regulatory Halt. The process for initiating a Regulatory Halt is set forth in Section X.D of the Amended Nasdaq UTP Plan. First, the proposed rule makes clear that the start time of a Regulatory Halt is the time the Primary Listing Market declares the Halt, regardless of whether communications issues impact the dissemination of notice of the Halt. The Exchange's experience in prior events is that market participants need certainty on the official start time of the Halt. Under the proposed rule, the start time is fixed by the Primary Listing Market; it is not dependent on whether notice is disseminated immediately. This will avoid possible disagreement if the Halt time were tied to dissemination or receipt of notification, which may occur at different times. The Exchange recognizes that in situations where communication is interrupted, trades may continue to occur until news of the Halt reaches all Trading Centers. However, a fixed ''official'' Halt time will allow SROs to revisit trades after the fact and determine in a consistent manner whether specific trades should stand.

Currently, many Trading Centers and other market participants rely on automated, machine-readable trade halt messages disseminated by the SIP to automatically halt their order matching and order dissemination systems. While the Exchange disseminates these messages in other formats and posts the messages on its website, Nasdaq's experience is that these alternative means of communication have not been relied on by many market participants. Proposed Rule 4120(b)(2)(B) would provide advance notice in the manner set forth in the Amended Nasdaq UTP Plan. The Amended Nasdaq UTP Plan requires the Primary Listing Market to notify all other participants and the SIP using such protocols and other emergency procedures as may be mutually agreed to between the Operating Committee and the Exchange. The Exchange also must take reasonable steps to provide notice to market participants if the SIP Processor is unable to disseminate notice of the Halt or the Primary Listing Market is not open for trading. In such case, the notice would include:

- Proprietary data feeds containing quote and last sale information that the Primary Listing Market also sends to the applicable SIP that is unable to disseminate the halt notices;
- Posting on a publicly available Exchange website; or
- System status messages that are disseminated to market participants who choose to sign up for the service.

The Exchange believes that market participants will benefit from additional sources of halt notifications that include machine readable and easily accessible communications for human traders and Nasdaq recommends that participants be prepared in advance to monitor multiple sources. Although it may take longer for participants to react to messages received in less automated formats, the use of multiple forms of dissemination will increase the likelihood that participants receive important information. It will also assist participants who do not subscribe to the Exchange's proprietary feeds in getting regulatory notices. As noted above, in situations where communication is interrupted the Exchange and other SROs would retain the ability to break trades that occurred after the start of the Regulatory Halt in appropriate circumstances (pursuant to rules governing clearly erroneous trades, at Equity 11, Rule 11890), thereby lessening the potential impact on participants that were delayed in halting trading. Plan participants must monitor several sources of regulatory notices so that they are aware of the imposition of a Regulatory Halt in situations where communication is interrupted; however, the failure of a Plan participant to do so will not prevent the Exchange from initiating a Regulatory Halt.

Proposed Rule 4120(b)(2)(C) also makes clear that, consistent with the Amended Nasdaq UTP Plan, except in exigent circumstances, the Primary Listing Market will not declare a Regulatory Halt retroactive to a time earlier than the notice of such halt. Feedback from market participants has been that it is very disruptive to trading when the Primary Listing Market sets the start of a trading halt for a time earlier than the notice of the halt.[39] Therefore, in almost all situations the trading halt will start at the time of the notice or at a point in time thereafter. However, the Exchange retains the authority to implement a retroactive halt to deal with unexpected and significant situations that represent exigent

[37] Current Rule 4120(a)(12)(G) (''If the Exchange is unable to reopen trading due to a systems or technology issue, it shall notify the Processor immediately'') will be incorporated into proposed Rule 4120(b)(4)(A)(i)e.6. (''If the Exchange is unable to reopen trading due to a systems or technology issue, it shall notify the SIP immediately'').

[38] By its terms, Rule 4120(a)(11) does not apply to rights and warrants, which are the only Nasdaq-listed securities that are not covered by the Limit Up-Limit Down Plan.

[39] As noted previously, the start of a Regulatory Halt is measured as the point in time when the Primary Listing Market declares the halt, regardless of whether there is a delay in dissemination of the notice or in receipt of the notice by participants.

circumstances. While it is difficult in advance to provide an exhaustive list of when retroactive application of a trading halt would be in the public interest, one situation where a halt was applied retroactively was when the Primary Listing Market erroneously lifted a Regulatory Halt. In that case, the Primary Listing Market instituted a Regulatory Halt retroactively so that it coincided with the time the original halt was lifted in error.

Consistent with Section X.C.2 of the Amended Nasdaq UTP Plan, Proposed Rule 4120(b)(D) states that in making a determination to declare a Regulatory Halt in trading any security for which the Exchange is the Primary Listing Market, the Exchange will consider the totality of information available concerning the severity of the issue, its likely duration, and potential impact on Members and other market participants and will make a good-faith determination that the criteria for declaring the Regulatory Halt have been satisfied and that a Regulatory Halt is appropriate. The Exchange will consult, if feasible, with the affected Trading Center(s), other SIP Plan Participants, or the Processor, as applicable, regarding the scope of the issue and what steps are being taken to address the issue.

Finally, consistent with Section X.C.2 of the Amended Nasdaq UTP Plan, Proposed Rule 4120(b)(2)(E) states that once a Regulatory Halt has been declared, the Exchange will continue to evaluate the circumstances to determine when trading may resume in accordance with its Rules.

Nasdaq notes that except as otherwise stated, the proposed procedures for initiating Regulatory Halts replace those set forth in current Rule 4120(c).

Regulatory Halt Initiated by Other Markets

The Exchange believes that consolidating all subsections concerning a Regulatory Halt declared by other Primary Listing Markets in Rule 4120(b)(3) would add clarity to the rule. As is the case under the current rule, the Exchange would honor a Regulatory Halt.

• Current Rule 4120(a)(2), which states that the Exchange may halt trading on Nasdaq in any security it trades on an unlisted trading privileges basis, if the Primary Listing Market declares a Regulatory Halt in the security to permit dissemination of material news, would become proposed Rule 4120(b)(3)(A)(i). Consistent with Section X.G of the Nasdaq UTP Plan, the proposed Rule will more broadly require Nasdaq to halt trading of a UTP security if the Primary Listing Market declares a Regulatory Halt in that security.

Current Rule 4120(b), which governs trading halts in certain Derivative Securities Products traded on the Exchange pursuant to unlisted trading privileges, would become proposed Rule 4120(b)(3)(A)(ii). Subsection (b)(3)(A)(ii) would replace the term ''Regular Market Session'' with the term ''Regular Trading Hours'' to stay consistent with other portions of the proposed rule. The change is non-substantive and would still refer to the period between 9:30 a.m. and 4:00 p.m. Eastern Time on days when the Exchange is open for trading. No other changes have been made to this subsection.

Resumption of Trading After a Regulatory Halt

The SROs have jointly developed processes to govern the resumption of trading in the event of a Regulatory Halt. While the actual process of re-launching trading will remain unique to each exchange (for example, trading in Nasdaq-listed securities resumes on the Exchange in most cases through a Halt Cross pursuant to Rule 4753), the proposed rule would harmonize certain common elements of the reopening process that would benefit from consistency across markets. These common elements include the primacy of the Primary Listing Market in resumption decisions, the requirement that the Primary Listing Market make its determination to resume trading in good faith,[40] and certain parts of the complex process of reopening trading after a SIP Halt. With respect to a SIP Halt, common elements of the reopening process include the interaction among SROs (including the Primary Listing Market with the SIP), the requirement that the Primary Listing Market terminate a SIP Halt with a notification that specifies a SIP Halt Resume Time, the minimum quoting times before resumption of trading, the cutoff time after which trading would not resume during Regular Trading Hours, and the time when trading may resume if the Primary Listing Market does not open a security within the amount of time specified in its rules after the SIP Halt Resume Time.

Proposed Rule 4120(b)(4) provides the process to be followed when resuming trading upon the conclusion of a Regulatory Halt. The new rule, which incorporates Section X.E, and .F of the Amended Nasdaq UTP Plan, is divided into the following three subsections concerning resumption of trading: (A) After a Regulatory Halt other than an IPO or SIP Halt;[41] (B) after a SIP Halt; and (C) after an IPO Halt.[42] The Exchange's proposed rule would make clear that Nasdaq, as the Primary Listing Market, is responsible for declaring a resumption of trading when it makes a good faith determination that trading may resume in a fair and orderly manner and in accordance with its rules. The Exchange expects that other SROs will propose the same concept. Similarly, the Exchange may resume trading in a non-Nasdaq-listed security;[43] subject to a Regulatory Halt after the Exchange receives notification from the Primary Listing Market that the Regulatory Halt has been terminated. The Exchange does not run Halt Crosses in securities listed on another exchange and, therefore, the resumption of trading in these securities will occur once notice from the Primary Listing Market is received. Proposed Rule 4120(b)(4)(A)(ii) sets forth the mechanics of how the resumption would occur for these non-Nasdaq-listed securities and is consistent with current practice.

The existing resumption process incorporating the Halt Cross is being moved to proposed Rule 4120(b)(4)(A)(i)a.–c.[44] This process will apply to any type of a Regulatory Halt except for halts related to the launch of IPOs and a SIP Halt (which does not exist under the current rule) or an LULD Halt. The existing process for launching IPOs has also been incorporated in the proposed rule without substantive modification as proposed Rule 4120(b)(4)(C).

[40] *See* Partial Amendment No. 1 of Trading Halt Amendments to the UTP Plan, dated March 31, 2021.

[41] When resuming trading in a halted security, the current Rule states that trading shall resume at the time specified by Nasdaq in a notice posted on a publicly available Nasdaq website. Consistent with the Amended Nasdaq UTP Plan, the Proposed Rule will provide that the Exchange will notify all participants and the SIP that a Regulatory Halt has been lifted using such protocols and other emergency procedures as may be mutually agreed to between the Operating Committee and the Exchange.

[42] The Exchange proposes to change an obsolete reference in the provision of the Rules pertaining to resumptions after IPO Halts. The Exchange proposes to replace the phrase ''member organizations'' with the word ''Member'' to reflect the fact that the Rules refer to Exchange participants as Members.

[43] Companies that are dually-listed on Nasdaq and NYSE have one Primary Listing Market. *See* proposed amended IM–5220. Thus, if Nasdaq is not the Primary Listing Market for a dually-listed security, it will resume trading after receiving notice from NYSE that the Regulatory Halt has been terminated.

[44] As proposed, Rule 4120(b)(4)(A)(i)a. will apply to all Regulatory Halts other than an IPO Halt or a SIP Halt.

Proposed Rule 4120(b)(4)(A)(i)d. states that during any trading halt or pause for which a halt cross under Rule 4753 will not occur (as in the case of a Regulatory Halt for securities where Nasdaq is not the Primary Listing Market), orders entered during the Regulatory Halt or pause will not be accepted, unless subject to instructions that the order will be directed to another exchange as described in Rule 4758.

The Exchange proposes to add Rule 4120(b)(4)(A)(i)e. that will address the re-opening process following a Limit Up-Limit Down pause. The Exchange is proposing to move the Limit Up-Limit Down trading pause termination process to Rule 4120(b)(4)(A)(i)e. unchanged from current Rule 4120(c)(10).

For a SIP Halt, proposed Rule 4120(b)(4)(B) establishes the process by which Nasdaq, as the Primary Listing Market, determines to resume trading. The SROs' experience with such events is that communication among SROs, SIPs and market participants is the best way to ensure that the Primary Listing Market has access to available information and to coordinate the reopening of trading in an orderly manner. In addition, the SROs anticipate that market participants and other impacted entities will have access to information about the issue causing the SIP Halt, the duration of the halt and the resumption process through updated communications from the SIP, Operating Committee and Primary Listing Market. The Operating Committees have policies and procedures that, among other things, establish industry notice protocols for various SIP-related events.[45]

Under the proposal, for the resumption of trading after a SIP Halt initiated by the Exchange, the Exchange, as the Primary Listing Market, will make a good-faith determination of the SIP Halt Resume Time, after considering the totality of information as to whether resuming trading would promote a fair and orderly market. Nasdaq would solicit input from the Processor, the Operating Committee, or the operator of the system in question (as well as any Trading Center(s) to which such system is linked), regarding operational readiness to resume trading. The Primary Listing Market retains discretion to delay the SIP Halt Resume Time if it has reason to believe that trading will not resume in a fair or orderly manner.

When resuming trading after a SIP Halt as the Primary Listing Market, Nasdaq will use the same Halt Cross as other Regulatory Halt types, except for a Regulatory Halt related to the launch of an IPO or an LULD Halt. Whereas the Halt Cross for other Regulatory Halt types (except for a Regulatory Halt related to the launch of an IPO or an LULD Halt, in which Nasdaq will extend the Display Only Period if an order imbalance exists at its conclusion) have a fixed five-minute Display Only Period during which the Exchange is open for quoting but not trading, the complexities in resuming trading after a SIP Halt require additional flexibility to assist market participants in events that may involve hundreds or even thousands of securities. As a result, proposed Rule 4120(b)(4)(B)(i)b. and c. sets a *minimum* five-minute Display Only Period that can be extended at the discretion of Nasdaq to ensure a fair and orderly reopening of trading. It is anticipated that Nasdaq will consider input from other SROs, the SIP and market participants in reaching this conclusion. The SROs considered setting a fixed-length Display Only Period, including a longer such period of ten or fifteen minutes, but it determined that a flexible time period would better serve the markets in that it could be five minutes, or longer if deemed appropriate to facilitate a fair and orderly reopening. Nasdaq would, of course, be expected to communicate the duration of the Display Only Period to market participants (*i.e.,* in the resumption notice) sufficiently in advance of resumption to allow them to prepare their systems for trading.

Proposed Rule 4120(b)(4)(B)(i)a. gives Nasdaq, as the Primary Listing Market, discretion to delay the SIP Halt Resume Time if it believes that trading will not resume in a fair and orderly manner. Moreover, proposed Rule 4120(b)(4)(B)(i)b allows Nasdaq to stagger the SIP Halt Resume Times for multiple securities in order to reopen in a fair and orderly manner. For example, this discretion could be used to open trading in a small number of symbols to ensure that systems are operating normally before resuming trading in the remaining symbols.

In addition, the proposed rule would establish the last SIP Halt Resume Time as 20 minutes before the end of Regular Trading Hours (*e.g.,* 3:40 p.m. ET)—which is the latest time by which Nasdaq believes that it could conduct an orderly Halt Cross process before the end of Regular Trading Hours and without impacting the Closing Cross. If trading has not resumed by that time, Nasdaq would establish its closing price in halted securities using its contingency closing process. The Exchange's contingent closing process is memorialized in Rule 4754(b)(7).

Proposed Rule 4120(b)(4)(B)(i)c. provides that, for a SIP Halt initiated by Nasdaq, the reopening process shall be the same as for a non-IPO Regulatory Halt pursuant to proposed Rule 4120(b)(4)(A)(i)a.–c., except that the Display Only Period will be a minimum of five minutes, but may be extended at the discretion of Nasdaq pursuant to proposed Rule 4120(b)(4)(B)(i)a.&b.

Proposed Rule 4120(b)(4)(B)(i)d. states that, for a SIP Halt initiated by Nasdaq, if during Regular Trading Hours, Nasdaq does not resume trading in a security for which it is the Primary Listing Market within 10 minutes after the SIP Halt Resume Time, then other markets may resume trading in that security. Nasdaq notes that this 10 minute time period corresponds to a similar 10 minute time period set forth in the Limit Up-Limit Down Plan after which the Processor may update price bands for paused securities if the primary listing market for such security is unable to reopen trading following a trading pause due to a systems or technology issue.[46]

Proposed Rule 4120(b)(4)(B)(ii) provides that, for a SIP Halt initiated by another exchange that is the Primary Listing Market, during Regular Trading Hours, Nasdaq may resume trading after trading has resumed on the Primary Listing Market or notice has been received from the Primary Listing Market that trading may resume. Proposed Rule 4120(b)(4)(B)(ii) provides that, for a SIP Halt initiated by a market other than Nasdaq, during Regular Trading Hours, if the Primary Listing Market does not open a security within the amount of time listed by the rules of the Primary Listing Market, Nasdaq may resume trading in that security. Under Proposed Rule 4120(b)(4)(B)(ii), Outside of Regular Trading Hours, Nasdaq may resume trading immediately after the SIP Halt Resume Time.[47]

Nasdaq notes that except as otherwise stated, the proposed procedures for terminating Regulatory Halts replace those set forth in current Rule 4120(c).

Operational Halt

The Exchange proposes in Rule 4120(c) to address Operational Halts,

[45] *See https://www.utpplan.com/DOC/UTP_SIP_Emergency_Procedures.pdf.*

[46] *See* Plan to Address Extraordinary Market Volatility Submitted to the Securities and Exchange Commission Pursuant to Rule 608 of Regulation NMS under the Securities Exchange Act of 1934, as amended (''Limit Up-Limit Down Plan''), Section VII(B)(4), at *https://assets.website-files.com/5fd0e55ae5f254cd291b2d35/5fd10d8e4c53d2024dd15f4f_LULD_Plan%20Amendment_20.pdf.*

[47] *See* Partial Amendment No. 2 of Trading Halt Amendments to the UTP Plan, dated April 7, 2021.

which are non-regulatory in nature and apply only to the exchange that calls the halt. The ability to call an Operational Halt has existed for a long time, although in the Exchange's experience, such halts have rarely been initiated. As part of Nasdaq's assessment with the other SROs of the halting and resumption of trading, the Exchange believes that the markets would benefit from greater clarity regarding when an Operational Halt may be appropriate. In part, the proposed change is designed to cover situations similar to those that might constitute a Regulatory Halt, but where the impact is limited to a single market. For example, just as a market disruption might trigger a Regulatory Halt for Extraordinary Market Activity if it affects multiple markets, so a disruption at the Exchange, such as a technical issue affecting trading in one or more securities, could impact trading on the Exchange so significantly that an Operational Halt is appropriate in one or more securities. In such an instance, it would be in the public interest to institute an Operational Halt to minimize the impact of a disruption that, if trading were allowed to continue, might negatively affect a greater number of market participants. An Operational Halt does not implicate other trading centers.

As is currently the case in existing Rule 4120(a)(3)(B), proposed Rule 4120(c)(1)(C) gives discretion to the Exchange to impose an Operational Halt in a security listed on Nasdaq when a Primary Listing Market imposes an Operational Halt in a security that is a derivative or component of the Nasdaq-listed security. As discussed in relation to Derivative Securities Products, Nasdaq does not automatically halt trading—through either a Regulatory Halt or an Operational Halt—when component or derivative securities are halted. However, proposed Rule 4120(c)(1)(C), like the current rule, gives the Exchange authority to halt a security listed on Nasdaq if the impact of the component or derivative security on price discovery or the fair and orderly market in the Nasdaq-listed security is significant enough to warrant a trading halt. Factors would include whether trading in the security listed on Nasdaq is fair and orderly, the nature of the issue that triggered the Operational Halt(s) on the Primary Listing Market(s) in the component or derivative securities and whether the security that is subject to the Operational Halt continues to trade on other Trading Centers.

Proposed Rule 4120(c) also would authorize the Exchange to implement an Operational Halt for any security trading on Nasdaq, including a security listed elsewhere:

- If it is experiencing Extraordinary Market Activity on Nasdaq; or
- when otherwise necessary to maintain a fair and orderly market or in the public interest.

The Exchange is proposing to delete Rule 4120(a)(3)(A) that authorizes the Exchange to institute an ''operational trading halt'' in a security listed on another exchange when that exchange imposes a trading halt because of an order imbalance or influx. The Exchange believes this language could restrict its ability to follow an Operational Halt imposed by another market to a limited set of fact patterns. The Exchange believes that the broader language provided by the definition of Extraordinary Market Activity and the ability to initiate an Operational Halt when necessary to maintain a fair and orderly market will better serve the interests of investors by allowing the Exchange to act where appropriate.

Proposed Rule 4120(c)(2) provides the process for initiating an Operational Halt. Under the proposed rule, the Exchange must notify the SIP if it has concerns about its ability to collect and transmit Quotation Information or Transaction Reports, or if it has declared an Operation Halt or suspension of trading in one or more Eligible Security, pursuant to the procedures adopted by the Operating Committee.

Proposed Rule 4120(c)(3) will clarify how the Exchange resumes trading after an Operational Halt. Proposed Rule 4120(c)(3) provides that the Exchange would resume trading when it determines that trading may resume in a fair and orderly manner consistent with the Exchange's rules. Proposed Rule 4120(c)(3) includes one change from the current rule. Under the current rule, the Halt Cross process is used to resume trading after all halts in Nasdaq-listed securities, whether the halt is a Regulatory Halt or an Operational Halt. The Exchange is proposing to modify the process for an Operational Halt to give the Exchange discretion to open trading without a Halt Cross if it determines such action to be in the best interests of the market. During the July 8, 2015 suspension of trading by NYSE in all securities due to an operational issue, many market participants requested that NYSE resume trading without an auction to avoid any impact on Regulation NMS compliance and mispricing because trading continued on other markets. NYSE determined that its rules (NYSE Rule 7.35A) allow it to reopen without an auction process, and this decision was well received. Indeed, Nasdaq agrees that a Halt Cross in such a circumstance might prove to be disruptive or result in trade-throughs. Nasdaq's current rules would not permit it to reopen after an Operational Halt without a Halt Cross auction process. The Exchange proposes modifying its rules to provide it the same flexibility.

For Nasdaq-listed securities where a Halt Cross is conducted, the Exchange will use the same Halt Cross process for resumption outlined in Rule 4120(b)(4)(A)(i)a.–c. as it does for most Regulatory Halt types. The proposed rule notes that Nasdaq may determine to open trading without a Halt Cross if it determines such action to be in the best interests of the market. Where the Exchange decides not to hold a Halt Cross for a security subject to a halt or pause, the Exchange proposes to amend Rule 4753 to clarify that market hours trading will resume when Nasdaq releases the security. Moreover, where trading halt or pause for which a halt cross will not occur (such as in the case of an Operational Halt for securities where Nasdaq is not the Primary Listing Market), orders entered during the Operational Halt will not be accepted, unless subject to instructions that the order will be directed to another exchange as described in Rule 4758.[48] When the Nasdaq is not the Primary Listing Market, when halting trading based on an Operational Halt, initiated by the Primary Listing Market, Nasdaq shall resume trading once it has determined the trading may be resumed in a fair and orderly manner.

Conforming Changes to Other Rules

The Exchange is proposing to modify a number of other rules that cross reference Rule 4120 in light of the reorganization of these rules. Updated cross references are proposed for the following rules:

- Rule 4702(a) (Order Types) will be modified to update cross references to the Rule that governs Limit-Up-Limit-Down procedures. Rule 4702(b)(16)(A) will be modified to update the cross-reference to the provision within Rule 4120 that is used to set the price of a Company Direct Listing Order.
- Rule 4753(a)(3) (Nasdaq Halt Cross) will be updated to make conforming changes to cross-references to IPO Halt procedures, a Trading Pause initiated pursuant to the Limit Up-Limit Down

[48] The Exchange notes that it does not plan to carry over a portion of the existing Rule text that permits Nasdaq, in the event that it halts trading pursuant to an operational trading halt imposed by another exchange, to commence quotations and trading at any time following initiation of operational trading halts, without regard to regular procedures for resuming trading. This language will be replaced.

procedure, and the definition of the terms ''Auction Reference Prices'' and ''Auction Collars.''

• Rule 4753(b) (Nasdaq Halt Cross) will be modified to update the references to subsections of Rule 4120 to reflect the reorganization of Rule 4120. Going forward, the Exchange will generally refer to Rule 4120 in the proposed amended Rule, rather than to specific subsections, to reflect the intended comprehensive scope of Rule 4753 to the halts described in Rule 4120.[49] The Exchange also updates a cross-reference to Rule 4120 discussed when describing the role of a ''financial advisor.'' [50]

• Rule 4753(c) (Nasdaq Halt Cross) will be modified to update a cross reference to Rule 4120.

• Rule 4754(b)(6) (Nasdaq Closing Cross related to the Limit Up-Limit Down Plan) will be modified to reflect the new subsections of Rule 4120 that govern LULD Halts.

• IM–5315–2, IM–5405–1, and IM–5505–1 will be modified to reflect updated cross-references to provisions of Rule 4120 that the Exchange is proposing to relocate.

In addition, the Exchange is proposing to amend several rules that rely on the definition of ''Regular Market Session'' in current Rule 4120(b)(4)(D). Regular Market Session is defined as ''the trading session from 9:30 a.m. until 4:00 p.m. or 4:15 p.m.'' The Exchange is proposing to replace the references to Regular Market Session in Rule 5710 (Securities Linked to the Performance of Indexes and Commodities (Including Currencies)) and 5711 with references to Regular Trading Hours as proposed in Rule 4120(a)(12). The term ''Regular Trading Hours'' would be consistent with the existing application of the definition of ''Regular Market Session'' and obviate the need for multiple definitions for the regular trading day. As previously discussed, no securities traded on Nasdaq currently close at 4:15 p.m. and, therefore, the alternative closing time in the current Regular Market Session definition is not needed.

The Exchange also is proposing to modify IM–5220, which covers dually-listed securities, to reflect the changes proposed to Rule 4120. The proposed rule makes clear that the Primary Listing Market is the market on which the security has been listed longest. This clear statement has eliminated the need for the more specific citations to various subsections of Rule 4120 currently contained in IM–5220 because proposed Rule 4120 distinguishes between those securities for which Nasdaq is the Primary Listing Market and those securities for which Nasdaq is not. The Exchange is also eliminating language from the rule that references the Intermarket Trading System, which no longer exists. These changes are not substantive.

Finally, the Exchange proposes to amend certain references in Rule 5711, which governs the trading of certain derivative securities. The references to Regular Market Session would be changed to Regular Trading Hours throughout Rule 5711. This is consistent with changes made in other rules referring to Regular Market Session. The reference in subsection (i)(v)(B)(2) to the trading pauses contained in Rule 4120(a)(11) has been replaced with a citation to the Limit Up-Limit Down Plan, which now applies to these instruments (rather than Rule 4120(a)(11), which as discussed above, is obsolete). The reference in Rule 5711(j)(vi)(B)(5) to halting a series of Managed Trust Securities traded on the Exchange pursuant to unlisted trading privileges will be updated to reference the applicable section of the proposal, Rule 4120(b)(3)(A)(ii).

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[51] Specifically, the proposal is consistent with Section 6(b)(5) of the Act [52] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other SROs are seeking to adopt harmonized rules related to halting and resuming trading in U.S.-listed equity securities. The Exchange believes that the proposed rules will provide greater transparency and clarity with respect to the situations in which trading will be halted and the process through which that halt will be implemented and terminated. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. equities exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Based on the foregoing, the Exchange believes that the proposed rules are consistent with Section 6(b)(5) of the Act [53] because they will foster cooperation and coordination with persons engaged in regulating and facilitating transactions in securities.

As discussed previously, the Exchange believes that the various provisions of the proposed rules that will apply to all SROs are focused on the type of cross-market event where a consistent approach will assist market participants and reduce confusion during a crisis. Because market participants often trade the same security across multiple venues and trade securities listed on different exchanges as part of a common strategy, the Exchange believes that the proposed rules will lessen the risk that market participants holding a basket of securities will have to deal with divergent outcomes depending on where the securities are listed or traded. Conversely, the proposed rules would still allow individual SROs to react differently to events that impact various securities or markets in different ways. This avoids the ''brittle market'' risk where an isolated event at a single market forces all markets trading equities securities to halt or halts trading in all securities where the issue impacted only a subset of securities. By addressing both concerns, the Exchange believes that the proposed rules further the Act's goal of maintaining fair and orderly markets.

The Exchange believes that the proposed rules' focus of responsibility on the Primary Listing Market for decisions related to a Regulatory Halt and the resumption of trading is consistent with the Act, which itself imposes obligations on exchanges with respect to issuers that are listed. As is currently the case, the Primary Listing Market would be responsible for the many regulatory functions related to its listings, including the determination of when to declare a Regulatory Halt. While these core responsibilities remain with the Primary Listing Market, trading

[49] At a future date, the Exchange intends to submit a rule filing proposal to conform Rules in the 5000 Series which describe trading halts for certain products and Rule 4120.

[50] As discussed earlier, the Exchange also proposes to amend Rule 4753(b) to state that for Nasdaq-listed securities that are the subject of a trading halt or pause initiated pursuant to Rule 4120, the Nasdaq Halt Cross shall occur at the time specified under Rule 4120, unless Nasdaq determines not to hold a Halt Cross, pursuant to proposed Rule 4120(c)(3)(A). The proposed amendments also clarify that market hours trading will commence when the Nasdaq Halt Cross concludes, or in the case of a security for which Nasdaq determines not to hold a Halt Cross, when Nasdaq releases the security.

[51] 15 U.S.C. 78f(b).

[52] 15 U.S.C. 78f(b)(5).

[53] 15 U.S.C. 78f(b)(5).

in the security can occur on multiple exchanges that have unlisted trading privileges for the security or in the over-the-counter market, regulated by FINRA. These other venues are responsible for monitoring activity on their own markets, but also have agreed to honor a Regulatory Halt.

The proposed changes relating to Regulatory Halts would ensure that all SROs handle the situations covered therein in a consistent manner that would prevent conflicting outcomes in cross-market events and ensure that all Trading Centers recognize a Regulatory Halt declared by the Primary Listing Market. The changes are consistent with and implement the Amended Nasdaq UTP Plan. While the proposed rules recognize one Primary Listing Market for each security, the rules do not prevent an issuer from switching its listing to another national securities exchange that would thereafter assume the responsibilities of Primary Listing Market for that security. Similarly, the proposed rules set forth a fair and objective standard to determine which exchange will be the Primary Listing Market in the case of dually-listed securities: The exchange on which the security has been listed the longest.

The Exchange believes that the other definitions in the proposed rules are also consistent with the Act. For example, existing rules of the Exchange allow it to take action to halt the market in the event of Extraordinary Market Activity. The proposed rules would expand the scope of what constitutes Extraordinary Market Activity, consistent with the amended definition of that term in the Amended Nasdaq UTP Plan, thereby furthering the Act's goal of promoting fair and orderly markets. The Exchange is also proposing to adopt definitions for ''SIP Outage,'' ''Material SIP Latency'' and ''SIP Halt,'' to explicitly address situations that may disrupt the markets, and these definitions are identical to the definitions in the Amended Nasdaq UTP Plan. The proposed rules provide guidance on when the Exchange should seek information from the Operating Committee, other SROs and market participants as well as means for dissemination of important information to the market, consistent with the Amended Nasdaq UTP Plan. The Exchange believes these provisions strike the right balance in outlining a process to address unforeseen events without preventing SROs from taking action needed to protect the market.

The Exchange believes that the proposed rules, which make halts more consistent across exchange rules, is consistent with the Act in that it will foster cooperation and coordination with persons engaged in regulating the equities markets. In particular, the Exchange believes it is important for SROs to coordinate when there is a widespread and significant event, as multiple Trading Centers are impacted in such an event. Further, while the Exchange recognizes that the proposed rule will not guarantee a consistent result on every market in all situations, the Exchange does believe that it will assist in that outcome. While the proposed rules relating to Regulatory Halts focuses primarily on the kinds of cross-market events that would likely impact multiple markets, individual SROs will still retain flexibility to deal with unique products or smaller situations confined to a particular market. To that end, the Exchange has retained existing elements of Rule 4120 that focus on its unique products and the processes it has developed over time to interact with its issuers.

Also consistent with the Act, and with the Amended Nasdaq UTP Plan, is the Exchange's proposal in Rule 4120(c) to address Operational Halts, which are non-regulatory in nature and apply only to the exchange that calls the halt. As noted earlier, the Exchange presently has the ability to call an Operational Halt, but does so rarely. The Exchange believes that the markets would benefit from greater clarity regarding when an Operational Halt may be appropriate. In part, the proposed change is designed to cover situations similar to those that might constitute a Regulatory Halt, but where the impact is limited to a single market. For example, just as a market disruption might trigger a Regulatory Halt for Extraordinary Market Activity if it affects multiple markets, so could a disruption at the Exchange, such as a technical issue affecting trading in one or more securities, impact trading on the Exchange so significantly that an Operational Halt is appropriate in one or more securities. In such an instance, it would be in the public interest to institute an Operational Halt to minimize the impact of a disruption that, if trading were allowed to continue, might negatively affect a greater number of market participants. An Operational Halt does not implicate other trading centers.

As is currently the case in existing Rule 4120(a)(3)(B), proposed Rule 4120(c)(1)(C) gives discretion to the Exchange to impose an Operational Halt in a security listed on Nasdaq when a Primary Listing Market imposes an Operational Halt in a security that is a derivative or component of the Nasdaq-listed security. As discussed in relation to Derivative Securities Products, Nasdaq does not automatically halt trading—through either a Regulatory Halt or an Operational Halt—when component or derivative securities are halted. However, proposed Rule 4120(c)(1)(C), like the current rule, gives the Exchange authority to halt a security listed on Nasdaq if the impact of the component or derivative security on price discovery or the fair and orderly market in the Nasdaq-listed security is significant enough to warrant a trading halt. Factors would include whether trading in the security listed on Nasdaq is fair and orderly, the nature of the issue that triggered the Operational Halt(s) on the Primary Listing Market(s) in the component or derivative securities and whether the security that is subject to the Operational Halt continues to trade on other Trading Centers.

Proposed Rule 4120(c) also would authorize the Exchange to implement an Operational Halt for any security trading on Nasdaq, including a security listed elsewhere: (i) If it is experiencing Extraordinary Market Activity on Nasdaq; or (ii) when otherwise necessary to maintain a fair and orderly market or in the public interest.

The Exchange believes that it is consistent with the Act to delete Rule 4120(a)(3)(A), which authorizes the Exchange to institute an ''operational trading halt'' in a security listed on another exchange when that exchange imposes a trading halt because of an order imbalance or influx. The Exchange believes this language could restrict its ability to follow an Operational Halt imposed by another market to a limited set of fact patterns. The Exchange believes that the broader language provided by the definition of Extraordinary Market Activity in proposed Rule 4120(c) will better serve the interests of investors by allowing the Exchange to act where appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposal is consistent with Section 6(b)(8) of the Act[54] in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act as explained below.

Importantly, the Exchange believes the proposal will not impose a burden on intermarket competition but will rather alleviate any burden on competition because it is the result of a collaborative effort by all SROs to harmonize and improve the process related to the halting and resumption of

[54] 15 U.S.C. 78f(b)(8).

trading in U.S.-listed equity securities, consistent with the Amended Nasdaq UTP Plan. In this area, the Exchange believes that all SROs should have consistent rules to the extent possible in order to provide additional transparency and certainty to market participants and to avoid inconsistent outcomes that could cause confusion and erode market confidence. The proposed changes would ensure that all SROs handle the situations covered therein in a consistent manner and ensure that all Trading Centers handle a Regulatory Halt consistently. The Exchange understands that all other Primary Listing Markets intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that its proposals concerning Operational Halts impose an undue burden on competition. Under the existing Rules, the Exchange already possesses discretionary authority to impose Operational Halts for various reasons, including because of an order imbalance or influx that causes another national securities exchange to impose a trading halt in a security, or because another national securities exchange imposes an operational halt in a security that is a derivative or component of a security listed on Nasdaq. As described earlier, the proposed Rule change clarifies and broadens the circumstances in which the Exchange may impose such Halts, and specifies procedures for both imposing and lifting them. The Exchange does not intend for these proposals to have any competitive impact whatsoever. Indeed, the Exchange expects that other exchanges will adopt similar rules and procedures to govern operational halts, to the extent that they have not done so already.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the provisions apply to all market participants equally. In addition, information regarding the halting and resumption of trading will be disseminated using several freely accessible sources to ensure broad availability of information in addition to the SIP data and proprietary data feeds offered by the Exchange and other SROs that are available to subscribers.

In addition, the proposals include several provisions related to the declaration and timing of trading halts and the resumption of trading designed to avoid any advantage to those who can react more quickly than other participants. The proposed rule gives the Exchanges the ability to declare the timing of a Regulatory Halt immediately. The SROs retain the discretion to cancel trades that occur after the time of the Regulatory Halt. The proposals also allow for the staggered resumption of trading to assist firms in reentering the market after a SIP Halt affecting multiple securities, in order to reopen in a fair and orderly manner. In addition, the proposals encourage early and frequent communication among the SROs, SIPs and market participants to enable the dissemination of timely and accurate information concerning the market to market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. 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–NASDAQ–2022–017 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–NASDAQ–2022–017. 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–NASDAQ–2022–017 and should be submitted on or before May 31, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09855 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34577; File No. 812–15280]

AFC BDC Inc., et al;

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: AFC BDC Inc., AFC Advisor LLC, AFC Management, LLC, AFC Investments, LLC, and AFC Gamma, Inc.

Filing Dates: The application was filed on November 8, 2021, and amended on November 17, 2021 and April 29, 2022.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving

[55] 17 CFR 200.30–3(a)(12).

the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on May 31, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Bernard Berman, *Bernie@Advancedflowercapital.com.*

FOR FURTHER INFORMATION CONTACT: Jill Ehrlich, Senior Counsel, or Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended and restated application, dated April 29, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Dated: May 3, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09849 Filed 5–6–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before June 8, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: Boots to Business is an entrepreneurial education initiative offered by the U.S. Small Business Administration (SBA) as a career track within the Department of Defense's revised Training Assistance Program called Transition Goals, Plans, Success (Transition GPS). The curriculum provides valuable assistance to transitioning service members exploring self-employment opportunities by leading them through the key steps for evaluating business concepts and the foundational knowledge required for developing a business plan. Participants are also introduced to SBA resources available to help access startup capital and additional technical assistance.

The Boots to Business Post Course surveys will be online, voluntary surveys that enable the Boots to Business program office to capture data related but not limited to the effectiveness of all Boots to Business courses, quality of the instructors and materials, and number of small businesses created as a result of participating in Boots to Business. Boots to Business will send an initial survey via email to all course participants immediately following course completion to gain insight on the quality of the program. Every 12 months following course completion, a follow up survey will be sent to all participants to measure participant outcomes as the SBA seeks to gauge the impact of course completion on the creation of veteran owned small businesses or the motivation and confidence of veterans to pursue business ownership. Participants will be surveyed once a year for 5 years following course completion to allow for business incubation.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control 3245–0390

Title: Boots to Business Entrepreneurship Survey for Service Members and Military Families.

Description of Respondents: Veteran owned small businesses.

Estimated Number of Respondents: 4,000.

Estimated Annual Responses: 4,000.

Estimated Annual Hour Burden: 667.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–09833 Filed 5–6–22; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11723]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Medieval Arms and Armor Galleries Rotation'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition ''Medieval Arms and Armor Galleries Rotation'' at the Cleveland Museum of Art, Cleveland, Ohio, and at possible additional exhibitions or venues yet to be determined, are of cultural significance and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of

State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–09871 Filed 5–6–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11724]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Cy Twombly: Making Past Present'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Cy Twombly: Making Past Present'' at The J. Paul Getty Museum at the Getty Center, Los Angeles, California; the Museum of Fine Arts, Boston, in Boston, Massachusetts; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW, (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–09870 Filed 5–6–22; 8:45 am]

BILLING CODE 4710–05–P

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meetings

TIME AND DATE: 9 a.m. ET on May 11, 2022.

PLACE: Charles Suber Banquet Hall, Young Harris College, 1 College Street, Young Harris, Georgia.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Meeting No. 22–02

The TVA Board of Directors will hold a public meeting on May 11, 2022, in the Charles Suber Banquet Hall at the Rollins Campus Center on the campus of Young Harris College, 1 College Street, Young Harris, Georgia. The meeting will be called to order at 9 a.m. ET to consider the agenda items listed below. TVA management will answer questions from the news media following the Board meeting.

On May 10, in the Charles Suber Banquet Hall at the Rollins Campus Center, the public may comment on any agenda item or subject at a board-hosted public listening session which begins at 2 p.m. ET and will last until 4 p.m. Preregistration is required to address the Board.

Agenda

1. Approval of minutes of the February 10, 2022 Board Meeting
2. Report of the Audit, Finance, Risk, and Cybersecurity Committee
3. Report of the Operations and Nuclear Oversight Committee
4. Report of the External Stakeholders and Regulation Committee
   A. Industrial Power Supply Arrangement
5. Report of the People and Governance Committee
   A. Board Code of Conduct
   B. Annual Compensation Plan Review Amendment
   C. Corporate Goals
6. Information Items
   A. Arrangements with a new industrial customer
   B. Creation of a new non-firm transmission service
7. Report from President and CEO

CONTACT PERSON FOR MORE INFORMATION: For more information: Please call Jim Hopson, TVA Media Relations at (865) 632–6000, Knoxville, Tennessee. Anyone who wishes to comment on any of the agenda in writing may send their comments to: TVA Board of Directors, Board Agenda Comments, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Dated: May 4, 2022.

Edward C. Meade,

Agency Liaison.

[FR Doc. 2022–10002 Filed 5–5–22; 11:15 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0131]

Entry-Level Driver Training: Application for Exemption; Ohio Department of Education

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT) .

ACTION: Notice of final disposition; denial of application for exemption.

SUMMARY: FMCSA announces its decision to deny the Ohio Department of Education's (ODE) request for an exemption from the Entry-Level Driver Training (ELDT) requirements. The exemption request applies to drivers, trained through ODE's ''Pre-Service School Bus Driver Training'' curriculum, who are seeking to obtain their Class B Commercial Driver's License (CDL) with school bus (S), passenger (P), and air brake endorsements and to current Class B CDL holders wishing to add the P and S endorsements. The ODE believes the Ohio theory (*i.e.,* classroom) curriculum and behind-the-wheel (BTW) instruction meet or exceeds all the standards of the 49 CFR 380 subpart F, ELDT requirements. FMCSA analyzed the exemption application and public comments and determined that the application provided no evidence that the exemption would ensure a level of safety equivalent to or greater than that achieved absent such exemption.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division, Office of

Carrier, Driver, and Vehicle Safety Standards, (202) 366–2722, *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, go to *www.regulations.gov,* insert the docket number ''FMCSA–2021–0131'' in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click ''Browse Comments.''

To view documents mentioned in this notice as being available in the docket, go to *www.regulations.gov,* insert the docket number ''FMCSA–2021–0131'' in the keyword box, click ''Search,'' and chose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (§ 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (§ 381.305). The decision of the Agency must be published in the **Federal Register** (§ 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (§ 381.300(b)).

III. Background

Current Regulation(s) Requirements

FMCSA's entry-level driver training (ELDT) regulations set forth minimum training standards for certain individuals applying for a Class A or Class B CDL for the first time; an upgrade of their CDL (*e.g.,* a Class B CDL holder seeking a Class A CDL); or a hazardous materials (H), passenger (P), or school bus (S) endorsement for the first time (49 CFR part 380, subpart F). These individuals are subject to the ELDT requirements and must complete a prescribed program of instruction provided by an entity that is listed on FMCSA's Training Provider Registry (TPR). The training requirements do not mandate a minimum number of theory (*i.e.,* classroom) or behind-the-wheel (BTW) hours for the completion of the Class A and B CDL or the S, P, or H endorsement curricula. FMCSA will submit driver-specific training certification information to State driver licensing agencies, which can administer CDL skills tests to applicants for the Class A and B CDL, and/or the P or S endorsements, or knowledge test for the H endorsement, only after verifying the driver completed the required training. The compliance date for the ELDT regulations is February 7, 2022.

Applicant's Request

The ODE requests an exemption from the ELDT requirements as set forth in 49 CFR part 380.[1] The exemption request applies to drivers, trained through ODE's ''Pre-Service School Bus Driver Training'' curriculum, who are seeking to obtain their Class B CDL with S, P, and air brake endorsements and to current Class B CDL holders wishing to add the P and S endorsements. If granted ODE requests that the exemption remain in effect as long as the Ohio Pre-Service theory and BTW curricula meet or exceed all the Federal training standards. The ODE states that the Ohio Pre-Service School Bus Driver Training program was established in 1978, and periodic review and upgrades to the program are continuous. With more than 25,000 school buses operated in Ohio, safety is of greatest importance for the ODE's Office of Pupil Transportation, and thousands of drivers are trained through the Department's program each year, including new and ''existing'' drivers seeking their initial CDL and applicable P and S endorsements.

The ODE's application explains that all drivers who operate school buses in Ohio must be listed in the ODE's School Foundation Payment System (SFPS) portal which tracks driver license information and assures drivers complete the necessary training requirements to transport students in Ohio. The SFPS verifies that drivers participated in both theory and BTW instruction and completes daily checks of driver certificates to ensure certificates are not expired. All drivers are required to attend theory training and have skill evaluations at least every 6 years. Most drivers are evaluated annually by their supervisors and/or on-the-bus instructors.

The ODE contends that without this requested exemption, ''Ohio school bus drivers would be required to have more training than anyone in the industry.'' School bus drivers who complete the Ohio Pre-Service School Bus Driver Training meet all the criteria to operate any Group-B commercial motor vehicle (CMV). This training program enables a driver to obtain a Class B CDL and provides the training to obtain either the P, S, or air brake endorsements, which allow for the driver to operate multiple Group B-regulated CMVs.

IV. Method To Ensure an Equivalent or Greater Level of Safety

To ensure an equivalent level of safety, the ODE believes the current State revised and administrative codes that requires new Ohio school bus drivers to successfully complete 15 hours of theory instruction and a minimum of 12 hours of BTW instruction and the training instructors' credentials, exceeds the requirements set forth in the ELDT regulations. The ODE's application also references the Ohio law requiring existing drivers to successfully complete 9 hours of theory instruction once every 6 years after initial certification, and requiring school bus drivers to complete a minimum of 4 hours of annual in-service training specific to the operation of a school bus, as additional elements that exceed the level of safety of the ELDT regulations.

V. Public Comments

On November 18, 2021, FMCSA published notice of this application and requested public comment (86 FR 64591). The Agency received 91 comments. Eighty-five commenters supported the exemption request broken

[1] ODE did not specify which subparts within 49 CFR part 380 are included within the scope of its application for exemption. However, based on the application's reference to ''the new Entry Level Driver Training regulations,'' FMCSA interprets that ODE is requesting exemption from 49 CFR part 380, subpart F, which includes the ELDT requirements for drivers as set forth in § 380.609.

down as follows: 59 individuals/drivers, 24 schools/school districts, the Pennsylvania Department of Transportation, and the ODE. Most of those expressing support for the application—primarily individuals/drivers or training schools in the State of Ohio—repeatedly commented that the ODE training regulations for school bus drivers in Ohio already exceed the requirements set forth in the impending Federal ELDT regulations.

The Commercial Vehicle Training Association (CVTA) and the National Association of Publicly Funded Truck Driving Schools (NAPFTDS), opposed the request. Also, Ancora Education and Roehl Transportation (Ancora/Roehl) expressed opposition to the request. In their jointly submitted comments, the CVTA and NAPFTDS stated: ''The safety of children being transported to and from school is not negotiable and should not be part of any discussion that does not adhere to the highest level of commercial driver and passenger training standards. The ELDT rule was created for this very purpose. The ELDT rule seeks to improve the quality of CDL training and the safety of drivers nationwide by mandating uniform standards that apply to all new CDL applicants. The ODE must be held to the same standard as all other entities, especially those who transport children.''

Ancora/Roehl also opposed application in their jointly filed comments, stating: ''The petitioners claim that Ohio Pre-Service theory and BTW meet or exceed all Federal standards and that they should be exempt from ELDT. We believe that in the interest of transparency, improving safety on our busy roads that they should be held to the same rules as everyone else. If the ODE does, in fact, 'meet and exceed' the ELDT requirements there is no reason as to why they cannot participate in the Training Provider Registry (TPR) as any other training provider. If FMCSA, grants this exemption we fear that this will lead to more exemptions, further exposing our children to unsafe drivers and road conditions.'' Four other commenters offered no position either for or against the ODE request, including the National School Transportation Association.

VI. FMCSA Safety Analysis and Decision

FMCSA evaluated the ODE application and the public comments and denies the exemption request. When the Agency originally established the ELDT rule, the Entry-Level Driver Training Advisory Committee agreed to the rule's core provisions through the Negotiated Rulemaking process. Furthermore, the Moving Ahead for Progress in the 21st Century (MAP–21) legislative statute which mandated the establishment of this rule, did include the passenger (P) endorsement within the scope of required ELDT. In light of the fact that 49 CFR part 383 currently requires that anyone seeking to obtain an S endorsement must also obtain a P endorsement, including the S endorsement training requirements in the ELDT final rule is entirely consistent with MAP–21. FMCSA believes that the S curriculum in the final rule will improve safety by providing a more complete approach to training that involves the transportation of all CMV passengers, including school children.

FMCSA does not believe the ELDT rule unduly burdens those jurisdictions that already maintain reasonable S training requirements. States or localities currently requiring that school bus drivers obtain S training that meets or exceeds the minimum standard established by the ELDT rule will be minimally impacted because the rule does not impose additional training requirements on those programs. Any provider who currently offers S endorsement training that is equivalent to, or more stringent than, the curriculum set forth in the ELDT rule is eligible for listing on the TPR, presuming all instructor qualifications and other requirements are met. Entities eligible for listing on the TPR include, for example, individual school districts, State agencies or departments, and third parties that contract with States or localities. The two commenters in opposition CVTA/NAPFTDS and Ancora/Roehl commented to these same points, and the Agency concurs with these commenters.

The ODE application does not provide an analysis of the safety impacts the requested exemption from the ELDT regulations may cause, and also does not provide adequate countermeasures to be undertaken to ensure that the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulations. Furthermore, through the Negotiated Rulemaking process, and the normal Agency notice and comment process for finalizing the ELDT rule, these provisions were agreed upon by the participants.

For these reasons, FMCSA denies the request for exemption.

Robin Hutcheson,

Deputy Administrator.

[FR Doc. 2022–09882 Filed 5–6–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0021]

Agency Information Collection Activity: VA Loan Electronic Reporting Interface (VALERI) System and Title Requirements for Conveyance of Real Property to the Secretary

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 8, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0021'' 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. 2900–0021'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the

information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 CFR 36.4338(a).

Title: VA LOAN ELECTRONIC REPORTING INTERFACE (VALERI) SYSTEM and TITLE REQUIREMENTS FOR CONVEYANCE OF REAL PROPERTY TO THE SECRETARY.

OMB Control Number: 2900–0021.

Type of Review: Revision.

Abstract: VA is submitting this modification to address information collection in the event loss mitigation efforts are unsuccessful and a VA-guaranteed loan goes into foreclosure. Statutory requirements for conveyance of properties to the Secretary are found in chapter 37 of title 38, United States Code. The implementing regulations are found in part 36 of title 38, Code of Federal Regulations (CFR). In 38 CFR 36.4323, titled ''Election to convey security'', VA explains that each conveyance or transfer of real property to the Secretary pursuant to this section shall be acceptable if:

The holder thereby covenants or warrants against the acts of the holder and those claiming under the holder (*e.g.,* by special warranty deed); and

It vests in the Secretary or will entitle the Secretary to such title as is or would be acceptable to prudent lending institutions, informed buyers, title companies, and attorneys, generally, in the community in which the property is situated.

Affected Public: Individuals or Households.

Estimated Annual Burden: 3,027 hours.

Estimated Average Burden per Respondent: 11 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 16,509.

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. 2022–09891 Filed 5–6–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0865]

Agency Information Collection Activity: Certification Requirements for Funeral Honors Providers

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: National Cemetery Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed 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 July 8, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian Hurley, National Cemetery Administration (42E), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Brian.Hurley1@va.gov.* Please refer to ''OMB Control No. 2900–0865'' 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. 2900–0865'' 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, NCA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of NCA's functions, including whether the information will have practical utility; (2) the accuracy of NCA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C.2402 and 38 U.S.C. 2404; 38 CFR 38.619.

Title: Certification Requirements for Funeral Honors Providers.

OMB Control Number: 2900–0865.

Type of Review: Extension of a currently approved collection.

Abstract: This information (VA Form 40–10190) is needed to ensure that funeral honors activities performed on VA property maintain the honor and dignity of the national cemetery and do not negatively impact the safety of cemetery visitors. 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.

Affected Public: Individuals or households.

Estimated Annual Burden: 32 hours.

Estimated Average Burden per Respondent: 5 minutes each.

Frequency of Response: One-time.

Estimated Number of Respondents: 380.

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. 2022–09839 Filed 5–6–22; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4192–F, CMS–1744–F, and CMS–3401–F]

RIN 0938–AU30, 0938–AU31, and 0938–AU33

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations to implement changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. This final rule will also revise regulations related to dual eligible special needs plans (D–SNPs), other special needs plans, and cost contract plans. This final rule finalizes certain 2021 and 2022 Star Ratings provisions that were included in two interim final rules with comment period (IFC) that CMS issued on April 6, 2020, and September 2, 2020; other policies from those interim final rules will be addressed in other rulemakings.

DATES:

Effective dates: These regulations are effective on June 28, 2022, except for amendatory instructions 27 and 36 (regarding the definition of ''negotiated price'' at §§ 423.100 and 423.2305), which are effective January 1, 2024.

Applicability dates: The applicability date of the provisions in this rule is January 1, 2023, except as explained in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Marna Metcalf Akbar, (410) 786–8251, or Melissa Seeley, (212) 616–2329—General Questions.

Jacqueline Ford, (410) 786–7767—Part C Issues.

PartCandDStarRatings@cms.hhs.gov—Part C and D Star Ratings Issues.

Marna Metcalf-Akbar, (410) 786–8251—D–SNP Issues.

PartDPaymentPolicy@cms.hhs.gov—Part D Pharmacy Price Concession Issues.

MLRreport@cms.hhs.gov—MLR Issues.

SUPPLEMENTARY INFORMATION:

Acronyms

ACC Automated Criteria Check
AHC Accountable Health Communities
AKS Anti-kickback Statute
ANOC Annual Notice of Change
ARB At-Risk Beneficiaries
BBA Bipartisan Budget Act
CAHPS Consumer Assessment of Healthcare Providers and Systems
CAI Categorical Adjustment Index
CMS Centers for Medicare & Medicaid Services
COI Collection of Information
COVID–19 Coronavirus 2019 Disease
C–SNP Chronic Condition Special Needs Plan
DME Durable Medical Equipment
D–SNP Dual Eligible Special Needs Plan
EGWP Employer Group Waiver Plan
EOC Evidence of Coverage
FAI Financial Alignment Initiative
FDR First-Tier Downstream and Related Entity
FFS Fee-for-Service
FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
FQHC Federally Qualified Health Center
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
HIPAA Health Insurance Portability and Accountability Act of 1996
HOS Health Outcomes Survey
HPMS Health Plan Management System
HRA Health Risk Assessment
HSD Health Service Delivery
ICR Information Collection Requirement
IRE Independent Review Entity
I–SNP Institutional Special Needs Plan
LOI Letter of Intent
LTSS Long Term Services and Supports
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACPAC Medicaid and CHIP Payment and Access Commission
MA–PD Medicare Advantage Prescription Drug
MCO Managed Care Organization
MCMG Medicare Communications and Marketing Guidelines
MACPAC Medicaid and CHIP Payment and Access Commission
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act
MLR Medical Loss Ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MMCO Medicare-Medicaid Coordination Office
MMP Medicare-Medicaid Plan
MOC Model of Care
MOOP Maximum Out-of-Pocket
NAMBA National Average Monthly Bid Amount
NEMT Non-emergency Medical Transportation
NMM Network Management Module
OACT Office of the Actuary
OMB Office of Management and Budget
PACE Programs of All-Inclusive Care for the Elderly
PAHP Prepaid Ambulatory Health Plan
PBP Plan Benefit Package
PDE Prescription Drug Event
PDP Prescription Drug Plan
PHE Public Health Emergency
PIHP Prepaid Inpatient Health Plan
PRA Paperwork Reduction Act
RFI Request for Information
RFA Regulatory Flexibilities Act
RHC Rural Health Clinic
SAE Service Area Expansion
SB Summary of Benefits
SDOH Social Determinants of Health
SHIP State Health Insurance Assistance Program
SNP Special Needs Plan
SSA Social Security Administration
SSBCI Special Supplemental Benefits for the Chronically Ill
TPMO Third-Party Marketing Organization

Additional information regarding the applicability dates: The Star Ratings provision at § 422.166(i)(12) is applicable to the calculation of the 2023 Star Ratings released in October, 2022, as discussed in section II.D.2. of this final rule. The definition of ''fully integrated dual eligible special needs plans (FIDE SNP)'' in § 422.2 at paragraphs (2)(i) and (iii) through (v), (5), and (6) as discussed in section II.A.5 of this final rule are applicable beginning January 1, 2025. The definition of ''highly integrated dual eligible special needs plans'' in § 422.2 at paragraph (3), as discussed in section II.A.5.f. of this final rule, is applicable beginning January 1, 2025. The applicability date of the requirements at § 422.101, as discussed in section II.A.4. of this final rule, is January 1, 2024. The requirements at § 423.100, as discussed in section II.H. of this final rule, are applicable beginning on January 1, 2024.

I. Executive Summary

A. Purpose

Over 29 million individuals receive their Medicare benefits through Medicare Advantage (MA or Part C), including plans that offer Medicare Prescription Drug Benefit (Part D) coverage. Over 23 million individuals receive Part D coverage through standalone Part D plans. The primary purpose of this final rule is to

implement changes to the MA and Part D programs. This final rule implements changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. This final rule also revises regulations related to dual eligible special needs plans (D–SNPs), other special needs plans, and Medicare cost contract plans.

B. Summary of Major Provisions

1. Enrollee Participation in Plan Governance (§ 422.107)

Managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.[1] Through this final rule, we require that any MA organization offering a D–SNP establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences. We also establish that the committee must include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. Public comments on our proposal reinforced our belief that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals.

2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of the Social Security Act (hereafter known as the Act) requires each special needs plan (SNP) to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs. We codified this requirement at § 422.101(f)(1)(i) as part of the model of care requirements for all MA SNPs. Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status. Many dually eligible individuals contend with multiple social risk factors such as homelessness, food insecurity, lack of access to transportation, and low levels of health literacy. Building on CMS's experience with other programs and model tests, and with broad support from public commenters, we are finalizing a requirement that all SNPs include one or more questions from a list of screening instruments specified in sub-regulatory guidance on housing stability, food security, and access to transportation as part of their health risk assessments (HRAs). However, based on public comments, we are not finalizing our proposal that all SNPs use the same specific standardized questions.

Our final rule will result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We believe this knowledge will better equip the MA organizations offering these SNPs to meet the needs of their members. Our final rule will also equip these MA organizations with person-level information that will help them better connect people to covered services, social service organizations, and public programs that can help resolve housing instability, food insecurity, or transportation challenges.

3. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage. We proposed several changes to how we define fully integrated dual eligible special needs plan (FIDE SNP) and highly integrated dual eligible special needs plan (HIDE SNP) to help differentiate various types of D–SNPs, clarify options for beneficiaries, and increase integration for these types of D–SNPs.

In this final rule, we are requiring, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicare cost-sharing and three specific categories of Medicaid benefits: Home health services (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and behavioral health services through a capitated contract between the State Medicaid agency and the Medicaid managed care organization that is the same legal entity as the MA organization that offers the FIDE SNP. In addition, we are requiring that, for plan year 2025 and subsequent years, each HIDE SNP have a service area that completely overlaps the service area of the affiliated Medicaid managed care plan with the capitated contract with the State. Consistent with existing policy outlined in sub-regulatory guidance, this final rule also codifies specific, limited carve-outs of the Medicaid long-term services and supports and Medicaid behavioral health services covered under the Medicaid capitated contract affiliated with FIDE SNPs and HIDE SNPs.

We believe these policies will create better experiences for beneficiaries and move FIDE SNPs and HIDE SNPs toward greater integration, which we believe is a purpose of the amendments to section 1859(f) of the Act regarding integration made by section 50311(b) of the BBA of 2018.

4. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) amended section 1859(f) of the Act to require that a D–SNP contract with the State Medicaid agency in each State in which the D–SNP operates to provide benefits, or arrange for the provision of Medicaid benefits, to which an individual is entitled. States have used these contracts to better integrate care for dually eligible individuals. In this final rule we codify new pathways through which States can use these contracts to require that certain D–SNPs with exclusively aligned enrollment (a) establish contracts that only include one or more D–SNPs within a State, and (b) use certain integrated materials and notices for enrollees. Where States choose this opportunity, it will help individuals better understand their coverage. Because Star Ratings are assigned at the contract level, this final rule will also provide a mechanism to provide States and the public with greater transparency on the quality ratings for the D–SNP(s), helping CMS and States better identify disparities between dually eligible beneficiaries and other beneficiaries and target interventions accordingly.

We also codify mechanisms to better coordinate State and CMS monitoring and oversight of certain D–SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems. Collectively, our proposals will improve Federal and State oversight of certain D–SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators.

[1] Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners.* Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf.*

5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)

In order to ensure that MA plan benefits do not discriminate against higher cost, less healthy enrollees, MA plans are required to establish a limit on beneficiary cost-sharing for Medicare Part A and B services after which the plan pays 100 percent of the service costs. Current guidance allows MA plans, including D–SNPs, to not count Medicaid-paid amounts or unpaid amounts toward this maximum out-of-pocket (MOOP) limit, which results in increased State payments of Medicare cost-sharing and disadvantages providers serving dually eligible individuals in MA plans. In this final rule we specify that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) must be calculated based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost-sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid (including cost-sharing that remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing). The change will result in more equitable payment for MA providers serving dually eligible beneficiaries. We project that our requirement as finalized will result in increased bid costs for the MOOP for some MA plans. A portion of those higher bid costs will result in increased Medicare spending of $3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of $2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals $600 million over 10 years. The net Federal 10-year cost estimate for the finalized requirement is $614.8 million.

6. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

In order to ensure enrollees have uninterrupted access to care, current regulations provide for special requirements at § 422.100(m) for MA plans during disasters or emergencies, including public health emergencies (PHEs), such as requirements for plans to cover services provided by non-contracted providers and to waive gatekeeper referral requirements. The timeframe during which these special rules apply can be very specific depending on the type or scope of the disaster or emergency, while other situations, like the PHE for COVID–19, may have an uncertain end date. Currently, the regulation states that a disaster or emergency ends (thus ending the obligation for MA plans to comply with the special requirements) the earlier of when an end date is declared or when, if no end date was identified in the declaration or by the official that declared the disaster or emergency, 30 days have passed since the declaration. This has caused some confusion among stakeholders, who are unsure whether to continue special requirements during a state of disaster or emergency after 30 days, or whether those special requirements do not apply after the 30-day time period has elapsed. In this final rule, we clarify the period of time during which MA organizations must comply with the special requirements. Under this final rule, MA organizations must ensure access for enrollees to covered services throughout the disaster or emergency period, including when the end date is unclear and the period renews several times, so long as there is a disruption of access to healthcare.

7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

We proposed to amend § 422.116 to require applicants to demonstrate that they meet the network adequacy standards for the pending service area as part of the MA application process for new and expanding service areas and to adopt a time-limited 10-percentage point credit toward meeting the applicable network adequacy standards for the application evaluation. Under our current rules, we require that an applicant attest that it has an adequate provider network that provides enrollees with sufficient access to covered services, and we will not deny an application based on the evaluation of the MA plan's network. Network adequacy reviews are a critical component for confirming that access to care is available for enrollees. As such, we believe that requiring applicants to meet network adequacy standards as part of the application process will strengthen our oversight of an organization's ability to provide an adequate network of providers to deliver care to MA enrollees. This change will also provide MA organizations with information regarding their network adequacy ahead of bid submissions, mitigating current issues with late changes to the bid that may affect the bid pricing tool. Finally, we understand that it may be difficult for applicants to have a full network in place almost 1 year ahead of the beginning of the contract as the proposed change for network adequacy rules will require. Therefore, the final rule includes a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for new or expanding service area applicants. Once the contract is operational, the 10-percentage point credit will no longer apply and MA organizations will need to meet full compliance.

We are finalizing our proposal, with one modification; to allow applicants to utilize Letters of Intent (LOIs) to meet network standards in counties and specialty types as needed. Once the contract is operational, MA organizations must have signed contracts with providers and facilities to be in full compliance.

8. Part C and Part D Quality Rating System

Due to the scope and duration of the COVID–19 PHE, we adopted a technical change to the 2022 Star Ratings methodology for extreme and uncontrollable circumstances in the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' published in the **Federal Register** and effective on September 2, 2020 (hereafter referred to as the ''September 2nd COVID–19 IFC''),[2] (CMS–3401–IFC; 85 FR 54820) at 42 CFR 422.166(i)(11) to make it possible for us to calculate 2022 Star Ratings for MA contracts. We proposed making a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey (87 FR 1842, January 12, 2022). Specifically, these measures are Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control. Without this technical change, CMS will be unable to calculate measure-level 2023 Star Ratings for these measures for any MA contract. We are therefore finalizing § 422.166(i)(12) without modification. In this final rule, we also respond to comments we received on the Medicare Advantage and Part D Star Ratings provisions in the interim final rules titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' published in the **Federal Register** on April 6, 2020,

[2] *www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient.*

with a March 31, 2020 effective date (hereafter referred to as the ''March 31st COVID–19 IFC'') [3] (85 FR 19230) and the September 2nd COVID–19 IFC. As detailed in sections II.D.3. and II.D.4. of this final rule, we are finalizing most of the Star Ratings provisions from the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC, but we are not finalizing several Star Ratings provisions in those interim final rules, regarding circumstances that did not happen, because they are moot. CMS will address other provisions from the interim final rules in other rulemakings.

9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)

In a previous rulemaking cycle, CMS modified the past performance methodology, revising the elements that are reviewed to determine if CMS should permit an organization to enter into a new contract or expand an existing contract. The current regulatory language prohibits an organization from expanding or entering into a new contract if it has a negative net worth or has been under sanction during the performance timeframe. In this final rule, we include an organization's record of Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.

10. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)

CMS has seen an increase in beneficiary complaints associated with third-party marketing organizations (TPMOs) and has received feedback from beneficiary advocates and stakeholders concerned about the marketing practices of TPMOs who sell multiple MA and Part D products. In 2020, we received a total of 15,497 complaints related to marketing. In 2021, excluding December, the total was 39,617. We are unable to say that every one of the complaints is a result of TPMO marketing activities, but based on a targeted search, we do know that many are related to TPMO marketing. In addition, we have seen an increase in third party print and television ads, which appears to be corroborated by State partners. Through this final rule, we will address the concerns with TPMOs by means of the following three updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V: (1) We define TPMOs in the regulation at §§ 422.2260 and 423.2260 to remove any ambiguity associated with MA plans/Part D sponsors responsibilities for TPMO activities associated with the selling of MA and Part D plans; (2) we add a new disclaimer that will be required when TPMOs market MA plans/Part D products (§§ 422.2267(e) and 423.2267(e)); and (3) we update §§ 422.2274 and 423.2274 to require additional plan oversight requirements associated with TPMOs, in addition to what is already required under §§ 422.504(i) and 423.505(i) if the TPMO is a first tier, downstream or related entity (FDR).

CMS' January 2021 final rule, entitled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (86 FR 5864) did not require notice and taglines, based on the HHS Office for Civil Rights repeal of certain notice and tagline requirements associated with section 1557 of the Affordable Care Act. In the months since the publication of this rule, CMS gained additional insight regarding the void created by the lack of these notification requirements. Based on the significant population (12.2 percent) of those 65 and older who speak a language other than English in the home and complaints CMS received through our Complaint Tracking Module, in this final rule we are finalizing a requirement that MA and Part D plans create a multi-language insert that will inform the reader, in the top fifteen languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area, that interpreter services are available for free. As a note, CMS provides plans a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S. As part of the finalized requirement, plans will be required to include the multi-language insert whenever a Medicare beneficiary is provided a CMS required material (for example, Evidence of Coverage, Annual Notice of Change, enrollment form, Summary of Benefits) as defined under §§ 422.2267(e) and 423.2267(e). We further note that existing statutes, including Section 504 of the Rehabilitation Act and 1557 of the Affordable Care Act, require the provision of any auxiliary aids and services required for effective communication for individuals with disabilities at no cost to the individual.

Finally, in this final rule we are codifying a number of current sub-regulatory communications and marketing requirements that were inadvertently not included during the previous updates to 42 CFR parts 422 and 423, subpart V.

11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460 and 423.2460)

To improve transparency and oversight concerning the use of Trust Fund dollars, we reinstate the detailed medical loss ratio (MLR) reporting requirements that were in effect for contract years 2014 to 2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. In addition, the new MLR reporting templates will require additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees under MA and Part D plans, and the impacts of recent rule changes that removed limitations on certain expenditures that count toward the 85 percent MLR requirement.

12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§§ 423.100 and 423.2305)

The ''negotiated prices'' of drugs, as the term is currently defined in § 423.100, must include all network pharmacy price concessions except those contingent amounts that cannot ''reasonably be determined'' at the point-of-sale. Under this exception, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a sponsor ultimately pays for a drug, based on the rationale that these amounts are contingent upon performance measured over a period that extends beyond the point of sale and thus cannot reasonably be determined at the point of sale. We proposed to eliminate this exception for contingent pharmacy price concessions (87 FR 1842, January 12, 2022). We proposed to delete the existing definition of ''negotiated prices'' at § 423.100 and to adopt a new definition for the term ''negotiated price'' at § 423.100, which we proposed to define as the lowest amount a pharmacy could

[3] *www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.*

receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy will receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). We proposed to allow plans the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale for applicable drugs in the coverage gap phase of the benefit. After consideration of the comments, we are modifying our proposal to apply the new definition of ''negotiated price'' to all phases of the Part D benefit, including the coverage gap phase. We are also amending the definition of ''negotiated price'' at § 423.2305 by revising paragraphs (1) and (2) of the definition of ''negotiated price'' for the Coverage Gap Discount Program to be consistent with the definition of ''negotiated price'' that we are adopting at § 423.100 (that is, the lowest possible reimbursement such network entity will receive, in total, for a particular drug). This policy takes effect 60 days after publication of the final rule and is applicable beginning on January 1, 2024. Part D sponsors will need to account for these changes in the bids that they submit for contract year 2024.

In this final rule, we add a definition of ''price concession'' at § 423.100. Although ''price concession'' is a term important to the adjudication of the Part D program, it had not yet been defined in the Part D statute, Part D regulations, or sub-regulatory guidance. We define price concession to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor.

C. Summary of Costs and Benefits

BILLING CODE 4120–01–P

Summary of Major Provisions of Rule	Description	Impact
1. Enrollee Participation in Plan Governance (§ 422.107)	We are finalizing a requirement that any MA organization must establish one or more enrollee advisory committees in each State where the organization offers a D-SNP to solicit direct input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.	There is on average an annual cost of $1.0 million on MA organizations for establishing and maintaining these D-SNP advisory committees, with a wide range of variability.
2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)	Building on CMS's experience with other programs and model tests, we are finalizing a requirement that all SNPs include questions on housing stability, food security, and access to transportation from a list of screening instruments specified by CMS in sub-regulatory guidance as part of their initial and annual health risk assessments beginning in contract year 2024.	For the initial year of implementation, there is a negligible impact on a portion of SNPs to update systems and HRA instruments.
3. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)	We are finalizing a requirement, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicare cost-sharing and Medicaid home health, medical supplies, equipment and appliances, and behavioral health services through a capitated contract with the State Medicaid agency. We are also finalizing a requirement that each HIDE SNP's capitated contract with the State apply to the entire service area for the D-SNP for plan year 2025 and subsequent years. Finally, consistent with existing policy outlined in sub-regulatory guidance, we are codifying specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.	There is a negligible one-time impact to update contracts.

Summary of Major Provisions of Rule	Description	Impact
4. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)	We are codifying new pathways through which States can use the State Medicaid agency contracts to require that certain D-SNPs with exclusively aligned enrollment (a) apply and request to establish contracts that only include one or more D-SNP within a State, and (b) integrate materials and notices for enrollees. We are also finalizing mechanisms to better coordinate State and CMS monitoring and oversight of certain D-SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems.	There is a one-time $1.1 million impact shared among the Federal Government, State governments, and MA organizations to create new contracts and to update systems to review the new materials.
5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)	We are finalizing that the maximum out-of-pocket limit in an MA plan (after which the plan pays 100 percent of MA costs) must be calculated based on the accrual of all cost-sharing in the plan benefit, whether that cost-sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid.	The policy will increase Medicare spending by $3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of $2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals $600 million over 10 years. The net 10-year cost estimate for the proposal is $614.8 million.
6. Special Requirements during a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))	We are clarifying the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services during a disaster or emergency (including PHEs) period, including when the end date is unclear and the period renews several times, so long as there is a disruption in access to healthcare for enrollees in the plan service area.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)	We are finalizing an amendment at § 422.116 to require an applicant to demonstrate compliance with network adequacy standards as part of the MA application process for new and expanding service areas and to adopt a time-limited 10 percentage point credit toward meeting the applicable network adequacy standards for the application evaluation. We are also finalizing a modification to our proposal to allow applicants to utilize Letters of Intent to meet network standards in counties and specialty types as needed.	In response to comments, we are allowing LOIs in lieu of full contracts during the application period to meet the network standards. This change will have negligible impact.
8. Part C and Part D Quality Rating System (§§ 417.472, 422.152, 422.164, 422.166, 422.252, 423.156, 423.182, 423.184, and 423.186)	We are finalizing a technical change at § 422.166(i)(12) without modification to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey. We also respond to comments and finalize certain Star Ratings provisions adopted in the March 31st COVID-19 IFC and the September 2nd COVID-19 IFC in sections II.D.3. and II.D.4. of this final rule.	None anticipated.
9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)	We are finalizing the inclusion of Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
10. Marketing and Communications Requirements on MA and Part D Plans to Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)	We are finalizing several updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V, to define MA plans/Part D sponsors responsibilities for TPMO activities associated with the selling of MA and Part D plans. We are finalizing a requirement that MA and Part D plans use a multi-language insert that will inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. We are also finalizing a requirement to include the multi-language insert whenever a Medicare beneficiary is provided a CMS required material as defined under §§ 422.2267(e) and 423.2267(e). Lastly, we are codifying a number of current sub-regulatory communications and marketing requirements.	There is an annual impact of $0.3 million on plans to print the multi-language insert.
11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460, 422.2490, and 423.2460)	To improve transparency and oversight concerning the use of Trust Fund dollars, we are reinstating the detailed MLR reporting requirements that were in effect for contract years 2014–2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount. In addition, we are finalizing the collection of additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees, and the impacts of recent rule changes.	MA organizations and Part D sponsors are expected to pay an additional $268.6 million in remittances to the Treasury over a 10-year period. There is an annual additional $2.3 million administrative cost to MA organizations and Part D sponsors for complying with these provisions, as well as a $0.2 million cost to the government for Federal contractors.

Summary of Major Provisions of Rule	Description	Impact
12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§§ 423.100 and 423.2305)	We are eliminating the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale for all phases of the Part D benefit. We are also deleting the existing definition of "negotiated prices" at § 423.100 and adopting a new definition for the term "negotiated price" at § 423.100, which we define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary. We are also modifying the definition of negotiated price in the coverage gap at § 423.2305 to align with the new definition of negotiated price at § 423.100. Lastly, we are adding a definition of "price concession" at § 423.100.	Requiring pharmacy price concessions in the negotiated price is expected to reduce total beneficiary costs by $26.5 billion between 2024 and 2032, or approximately 2 percent. In addition, the policy is estimated to have $46.8 billion in Part D costs for the government between 2024 and 2032 due to increases in direct subsidy and low-income premium subsidy payments, which represents a 3 percent increase. Manufacturers will save about $16.8 billion over the same period. We expect a one-time cost to plan sponsors of $0.1 million to update systems and ongoing costs of $0.1 million for added PDE transmission costs.

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D. Background

We received approximately 6,179 timely pieces of correspondence containing one or more comments for the provisions addressed in this final rule from the proposed rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' which appeared in the **Federal Register** on January 12, 2022 (hereafter referred to as the January 2022 proposed rule, 87 FR 1842). Comments were submitted by MA health plans, Part D sponsors, beneficiaries, MA enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, States, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, Members of Congress, and other vendor and professional associations.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based on the comments received. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings.

We received an overarching comment related to the proposed rule, which we summarize in the following paragraphs:

Comment: A commenter expressed a concern about the timing of the provisions included in the proposed rule related to the deadline for bid submissions, especially related to proposals with contract year 2023 effective dates. The commenter noted that several proposals would require operational and technical changes for MA organizations as well as additional resource allocations, and, as such, welcomed additional time for implementation. The commenter suggested it could better align and collaborate with CMS in the future if given more time to fully understand and implement proposed changes.

Response: We understand and appreciate the commenter's concerns and MA organizations and Part D sponsors' willingness to work to meet the implementation date timeframes. In response to comments, we are modifying the date on which some of the new and amended regulations in this final rule become applicable. We describe these modifications in further detail in the respective sections of the rule.

We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. As such, these out-of-scope public comments are not addressed in this final rule. The following paragraphs summarize the out-of-scope public comments.

A commenter noted that long-term care provider-led institutional special needs plans (I–SNPs) offer a strong additional solution to States in integrated efforts, especially for long-term care services uses with complex, high risk needs.

We received a few comments related to D–SNP look-alikes, which are addressed at § 422.514(d). A commenter requested that CMS consider reducing the threshold for a D–SNP look-alike from the current 80 percent of dually eligible individuals enrolled to 50 percent and requiring the Medicare program to inform individuals that they are enrolling in a non-integrated model where an integrated model exists. Without such action, this commenter expressed that D–SNP look-alikes could undermine progress on integration,

leading to the erosion of D–SNP enrollment over time and additional beneficiary confusion. Another commenter requested that CMS reconsider its current policy for States without a D–SNP option for partial-benefit dually eligible individuals by either allowing these individuals to enroll in FIDE SNPs or excluding them from the 80-percent threshold calculation used to determine D–SNP look-alikes in these States.

A few commenters encouraged CMS to consider applying other MMP design elements to D–SNPs. These included extending contract management teams to HIDE SNPs and FIDE–SNPs, D–SNPs with exclusively aligned enrollment, and/or D–SNPs with a meaningful proportion of enrollees who receive Medicaid benefits from a managed care plan affiliated with the D–SNP; requiring D–SNPs to develop single case agreement policies to enable enrollees to see out-of-network providers; applying MMP program audit rules and protocols to D–SNPs with exclusively aligned enrollment; and allowing beneficiaries to enroll in integrated plans on a monthly basis rather than the roughly quarterly enrollment opportunities under MA.

MACPAC noted that while the provisions in the proposed rule promote integration in existing products, they do not necessarily increase the availability of integrated models or enrollment in integrated plans and urged CMS to look for ways to expand policies to promote integration beyond D–SNPs with exclusively aligned enrollment in future rulemaking.

A commenter encouraged CMS to reconsider its approach to setting separate requirements for D–SNPs and Medicaid managed care plans and to align Federal regulations for FIDE SNPs with those that already exist for Medicaid managed care.

A commenter recommended that CMS take steps to reduce limitations on data sharing between plans and States and provide additional guidance on creating a standardized and electronic method to integrate information in model materials.

A few commenters recommended that CMS take steps to ensure that quality measurement is appropriately targeted to the populations served by each product and that measurement and related financial incentives do not disproportionately penalize D–SNPs for serving populations with greater risk factors. Other commenters urged CMS to require all States to adopt standardized, disability-informed quality measurement tools so that measures are collected and reported in a uniform format.

A few commenters expressed concern related to quality measurement for D–SNPs more broadly. A commenter stated that because of the challenges inherent to serving younger dually eligible beneficiaries with disabilities who represent the most complex and at-risk Medicare members with the most social risk factors, plans serving this population have less quality bonus funding available to support supplemental benefits tailored to the population.

A commenter suggested CMS consider revising the requirement that the D–SNP and Medicaid managed care plan contract holder must be the same legal entity in order to qualify as a FIDE SNP; instead, the commenter recommended using the same requirement that is used for HIDE SNPs that the contract holder is the same parent organization or another entity that is owned and controlled by its parent organization.

A few commenters requested CMS consider additional financial policies. A commenter encouraged CMS to require States to ensure that the capitated payments for HIDE SNPs and FIDE SNPs are documented in the State Medicaid agency contract. Another commenter noted that the existing risk adjustment methodology is not sensitive to pick up all of the nuances for D–SNPs that largely serve populations with more complex care. A commenter requested that CMS consider clarifying elements of the cost-sharing billing process during an enrollee's Medicare deeming period, including prohibiting Medicare cost-sharing being billed to dually eligible individuals during the Medicare deeming period.

A commenter requested guidance on how to handle cost-sharing for supplemental benefits that may overlap with what is provided by Medicaid.

A commenter expressed concern regarding the complaint resolution process for dually eligible individuals, noting that it is fragmented and confusing when some issues are handled by State Medicaid agencies or plans while others are handled by CMS or MA plans. The commenter noted that ''no wrong door'' policies for enrollee concerns are critical to ensuring complaints are addressed.

A commenter urged CMS to consider the limited availability of transportation options in rural communities when finalizing the proposed rule.

A commenter expressed interest in additional research to better understand fluctuations within dual eligibility and what may cause a partial-benefit dually eligible individual to become a full-benefit dually eligible individual and encouraged CMS to assess whether integrated models can help prevent partial-benefit dual eligible individuals from necessitating full-benefit status.

A commenter suggested that another approach to improving integrated care is to establish a single program that would provide dually eligible beneficiaries with their medical, long-term care, behavioral, and social needs. They further suggested the program allow States to contract with the administering entities, which would bear two-sided risk to ensure accountability and eliminate incentives for cost-shifting.

A commenter expressed concerns about the MA program overall, including inadequate care provided to MA enrollees, low payments to providers, and high MA payment rates compared to the original Medicare fee-for-service (FFS) program.

CMS received a number of comments regarding extending the COVID–19 disaster adjustments that all contracts received for the 2022 Star Ratings for measures other than HEDIS–HOS measures and reducing the weight applied to the patient experience/complaints and access measures for the 2023 Star Ratings.

CMS received many comments regarding network adequacy requirements and policies that are outside of the scope of this rule. Some commenters indicated that CMS should consider reinstating previous network adequacy standards including returning to the 90 percent rate of beneficiary requirements within time and distance standards for micro, rural and counties with extreme access considerations, as well as including dialysis facilities as a specialty type evaluated for network adequacy under § 422.116(b). Many commenters recommended that CMS add criteria to our current network adequacy standards. For example, commenters recommended that CMS add new provider and facility specialty types, including sub-specialty types, to our list of those which are evaluated for network adequacy standards under § 422.116(b). Some commenters suggested that CMS increase the frequency in which network adequacy formal reviews are conducted or align the triennial network adequacy review timelines with the application timeline. A commenter suggested that CMS integrate network adequacy into Star Ratings measures. A few commenters suggested that CMS consider how increased use of telehealth-provided services will impact network adequacy, and that CMS should consider expanding the telehealth credit in certain county types such as rural

counties. A few commenters recommended CMS establish policies to enhance information available in MA plan network directories. A commenter suggested that CMS consider changes and improvements to the network adequacy exceptions and criteria process. A commenter provided recommendations regarding how network adequacy standards should recognize and address the unique needs of enrollees in I–SNPs. A commenter recommended CMS develop network standards specific to the D–SNP population. Additional topics out of scope of this rule include requests to update timelines for release of the Reference and Sample Beneficiary Files, make MA organizations' network adequacy review data publicly available, and limit organization's ability to make changes to network providers throughout the contract year.

CMS received some comments regarding special requirements during emergency and disasters that are out of scope for this rule. A commenter asked CMS to provide guidance about online or point-of-sale processing of Part B out-of-network claims during a disaster or emergency. Another commenter expressed concerns that these requirements do not apply to Part D drugs.

A commenter suggested that we take a more holistic approach to past performance. The commenter suggested we review all contracts for past performance and not just applicants.

We received several out-of-scope comments related to the provision on applying all pharmacy price concessions to the negotiated price at the point of sale. A few commenters urged CMS to address pharmacy benefit managers' (PBMs') formularies, specifically the preference for brand medications over generics due to the rebates and with respect to the use of biosimilars as they launch. Many commenters asked that CMS address the ''reasonable and relevant'' contracting terms and conditions between MA organizations/plan sponsors and pharmacies. A few commenters expressed concern with vertical integration of PBMs and pharmacies. A few commenters were concerned about the costs of COVID–19 tests and treatments. Some commenters stated that CMS should not make the changes associated with this Pharmacy Price Concessions rule when it should instead be working to wind down or officially incorporate policies put in place during the COVID–19 PHE. Some commenters stated that the proposal failed to address the root cause of high drug prices and offered recommendations for regulating the pharmaceutical industry. A few commenters stated that PBMs should not set drug prices and encouraged CMS to make sweeping reforms including a patient bill of rights and a pharmacy bill of rights. A few commenters stated that PBMs cannot engage in sub-capitation arrangements that require pharmacies to bear risk. Some commenters requested CMS re-evaluate its policy on U.S. Food and Drug Administration (FDA)-approved anti-obesity medications. Other commenters recommended that CMS do more to improve access to the Part D Low-Income Subsidy (LIS) program, noting the program's importance to improving health equity and the nearly three million beneficiaries who are eligible for the program but not enrolled. This commenter also requested that CMS track and report on the number of complaints received regarding Part D plans charging individuals enrolled in the full LIS program the higher plan copayment rather than the established LIS copayment.

Unless otherwise noted, cites to regulations are to title 42 of the CFR.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Improving Experiences for Dually Eligible Individuals

1. Overview and Background

Over 11 million people are concurrently enrolled in both Medicare and Medicaid. Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in: (1) Missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation.[4]

''Integrated care'' refers to delivery system and financing approaches that—

- Maximize person-centered[5] coordination of Medicare and Medicaid services, across primary, acute, long-term, behavioral, and social domains;
- Mitigate cost-shifting incentives, including total-cost-of-care accountability across Medicare and Medicaid; and
- Create seamless experiences for beneficiaries.

We described at 87 FR 1849 through 1850 of the proposed rule a range of approaches to integrating Medicare and Medicaid benefits or financing for dually eligible individuals, including through demonstrations and existing programs. The most prevalent forms of integrated care use capitated financing, including capitation of health plans to cover the full range of Medicare and Medicaid services. The number of dually eligible individuals in integrated care or financing models or both has increased over time, now exceeding 1 million beneficiaries, but it remains the exception rather than the rule in most States.[6]

An increasing number of dually eligible individuals are enrolled in managed care plans. The broader trend toward managed care presents opportunities for integrated care. It also presents risks for further fragmentation and complexity. In fact, while enrollment in integrated care has increased, it is also becoming increasingly likely that dually eligible individuals are in one sponsor's Medicaid managed care organization (MCO) and a competitor's D–SNP. The result: Duplicative health risk assessments (HRAs); multiple ID cards, handbooks, and provider and pharmacy directories; strong incentives for cost-shifting where possible; multiple care coordinators; more complex billing processes for providers; and similar other fragmented care, burdens, or increased costs.

Section 2602 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) established the Medicare-Medicaid Coordination Office (MMCO) within CMS to better align and integrate benefits for dually eligible individuals.

[4] For example, see chapter 1 of Medicaid and CHIP Payment and Access Commission, *Report to Congress* on Medicaid and CHIP, June 2021, and chapter 12 of Medicare Payment Advisory Committee, *June 2019 Report to the Congress: Medicare and the Health Care Delivery System.*

[5] ''Person-centered care'' typically refers to focusing care on the needs of the individual and ensuring that a person's individual preferences, needs, and values guide care decisions. This is in contrast to approaches to care in which the specific diagnosis or illness drives care and treatment decisions. See the National Center on Advancing Person-Centered Practices and Systems for additional information: *https://ncapps.acl.gov/home.html.*

[6] CMS Medicare-Medicaid Coordination Office FY 2020 Report to Congress, available at: *https://www.cms.gov/files/document/reporttocongressmmco.pdf.*

Section 50311(b)(2) of the Bipartisan Budget Act (BBA) of 2018 amended that provision to also charge MMCO with—

- Developing regulations and guidance related to the integration or alignment of policy and oversight under Medicare and Medicaid regarding D–SNPs; and
- Serving as the single point of contact for States on D–SNP issues.

At 87 FR 1850 of the proposed rule, we described recent MA/Part D rulemaking to enhance D–SNPs. Despite this recent work, additional actions are needed to maximize the potential of D–SNPs to deliver person-centered integrated care—and ultimately better health outcomes and independence in the community—for dually eligible older adults, people with disabilities, and people with end stage renal disease. We are working to improve and increase options for more integrated care in a variety of ways, including through D–SNPs.

a. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6) of the Act, SNPs restrict enrollment to certain populations. The most common type of SNP is a dual eligible special needs plan, or D–SNP, in which enrollment is limited to individuals entitled to medical assistance under a State plan under title XIX of the Act.

D–SNPs are intended to integrate or coordinate care [7] for dually eligible individuals more effectively than standard MA plans or the original Medicare fee-for-service (FFS) program by focusing enrollment and care management on this population. As of January 2022, approximately 4.0 million dually eligible individuals (more than 1 of every 4 dually eligible individuals) were enrolled in 729 D–SNPs.[8]

Federal statute and implementing regulations have established several requirements for D–SNPs in addition to those that apply to all MA plans to promote coordination of care, including HRA requirements as described in section 1859(f)(5)(A)(ii)(I) of the Act and at 42 CFR 422.101(f)(1)(i), evidence-based models of care (MOCs) as described in section 1859(f)(5)(A)(i) of the Act and at 42 CFR 422.101(f), and contracts with State Medicaid agencies as described in section 1859(f)(3)(D) of the Act and at 42 CFR 422.107. The State Medicaid agency contracting requirement allows States to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets.

Most recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs, beginning in 2021, including minimum integration standards, coordination of the delivery of Medicare and Medicaid benefits, and unified appeals and grievance procedures for integrated D–SNPs, the last of which we implemented through regulation to apply to certain D–SNPs with exclusively aligned enrollment, termed ''applicable integrated plans.'' These requirements, along with clarifications to existing regulations, were codified in the ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' final rule (84 FR 15696 through 15744) (hereinafter referred to as the April 2019 final rule).[9]

For a more comprehensive review of D–SNPs and legislative history, see the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (85 FR 9018 through 9021), which appeared in the **Federal Register** on February 18, 2020.[10]

b. Medicare-Medicaid Plans

To test additional models of integrated care, we established the Medicare-Medicaid Financial Alignment Initiative (FAI) in July 2011 with the goal of improving outcomes and experiences for full-benefit dually eligible individuals while reducing costs for both States and the Federal Government. This State-Federal partnership is tested using authority under 1115A of the Act (as added by section 3021 of the Affordable Care Act) and further described below. Although the FAI includes two models, the model with the largest number of States participating is a capitated model through which CMS, the State, and health plans (called Medicare-Medicaid Plans or MMPs) enter into three-way contracts to coordinate the full array of Medicare and Medicaid services for members. Our proposed rule at 87 FR 1851 through 1854 summarized the key elements offered by MMPs under the capitated model demonstrations.

As discussed in the proposed rule at 87 FR 1851, CMS and States partnered with MMPs to create a seamless experience for beneficiaries, but MMPs operate as both MA organizations offering Medicare Advantage Prescription Drug (MA–PD) plans and Medicaid managed care organizations. As such, unless waived by CMS, MMPs are required to comply with Medicaid managed care requirements under 42 CFR part 438, with MA (also known as Part C) requirements in title XVIII of the Act as well as 42 CFR part 422 and, with regard to the Medicare prescription drug benefit, Part D requirements in title XVIII of the Act and 42 CFR part 423. Section 1115A of the Act (as added by section 3021 of the Affordable Care Act) authorizes waiver of certain Medicare provisions and CMS used that authority to waive several Medicare requirements for the FAI. For States participating in the capitated model, CMS typically uses authority under section 1115(a), 1915(b), 1915(c), or 1932(a) of the Act to waive or exempt the State from certain provisions of title XIX of the Act or establish the authority to deliver Medicaid services through managed care.

As of January 2022, there are 39 MMPs in nine States serving approximately 424,000 members.[11]

As summarized at 87 FR 1851 through 1854 in our proposed rule, while an independent evaluation of the FAI is still underway, we have already gleaned several lessons regarding integrated,

[7] ''Care coordination'' typically refers to the managing of care and sharing of information among medical and non-medical providers and supports across the spectrum primary, acute, behavioral health, long-term services and supports. See, for example, *https://www.ahrq.gov/ncepcr/care/coordination.html*, and Barth, S., Silow-Carroll, S., Reagan, Russell, M., Simmons, T. (2019) Care Coordination in Integrated Care Programs Serving Dually Eligible Beneficiaries—Health Plan Standards, Challenges and Evolving Approaches. Report to the Medicaid and CHIP Payment and Access Commission. *https://www.macpac.gov/wp-content/uploads/2019/03/Care-Coordination-in-Integrated-Care-Programs-Serving-Dually-Eligible-Beneficiaries.pdf.*

[8] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (January 2021). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[9] See *https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.*

[10] See *https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf.*

[11] MMP enrollment as of January 2022. See *CMS Monthly Enrollment by Contract Report* (January, 2022). Retrieved from *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/enrollment-contract-2022-01.*

managed care from the capitated financial alignment model:

- Enrollee participation in governance helps identify and address barriers to high-quality, coordinated care;
- Assessment processes are a vehicle for identifying and addressing unmet needs, particularly those related to social determinants of health;
- Medicare-Medicaid integration correlates with high levels of beneficiary satisfaction;
- Carving in Medicaid behavioral health benefits helps promote better coordination of behavioral health and physical health services;
- Integrated beneficiary communication materials can enhance the beneficiary experience;
- Effective joint oversight of integrated managed care products is possible;
- Integrated care and joint oversight provide a platform for quality improvement;
- There is potential for market distortions in areas with multiple options targeting the same population; and
- State investment is critical to successful implementation of integrated care either through MMPs or D–SNPs.

Since the outset of the FAI, our shared goal with State partners has been to develop models that promote greater Medicare-Medicaid integration that, if successful, could be implemented on a broader scale. We proposed to incorporate into the broader MA program many of the MMP practices that successfully improved experiences for dually eligible individuals.

2. Summary of D–SNP Proposals Related to MMP Characteristics

Many of the proposals in the proposed rule would incorporate certain MMP policies into the regulations governing D–SNPs or, in several cases, certain types of D–SNPs. We included a table (87 FR 1854) summarizing how our proposals relate to MMP policies. Section II.A.14 of this final rule includes an updated version of that table to reflect the policies adopted in this final rule.

Comment: Several commenters, including MACPAC, described the challenges dually eligible individuals and their providers and families experience navigating separate and fragmented Medicare and Medicaid delivery systems. A commenter noted suboptimal care coordination can compromise patient care and increase overall program spending. A commenter noted younger dually eligible individuals face health inequities caused by institutional racism and other systematic disadvantages. A few commenters encouraged full integration and MACPAC cited recent Bipartisan Policy Center reports [12] urging full integration of Medicare and Medicaid services for all full-benefit dually eligible individuals. Another commenter emphasized that coverage of medical, behavioral health, and long-term services and supports should be aligned and integrated care should be grounded in the diversity of dually eligible enrollees, tailored to individuals' needs and preferences, prioritize care coordination, simplify eligibility and enrollment processes, minimize administrative burdens, and honor enrollee choice of plan and providers.

Response: We appreciate the comments and we agree that a fragmented delivery system raises major issues, as we discussed in the proposed rule (87 FR 1849 through 1850). We are committed to maximizing opportunities for integration through the proposals finalized in this rule and will continue to explore additional ways to better align the Medicare and Medicaid programs in the future. We acknowledge the comment about dually eligible individuals experiencing health inequities caused by institutional racism and other systematic disadvantages. Addressing such inequity is a major focus of CMS and other Federal agencies, based in part on Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021).

Comment: Numerous commenters supported the overall focus of the proposals to better integrate Medicare and Medicaid services, incrementally strengthen and improve integration for D–SNPs, advance health equity, and improve the beneficiary experience for older adults and people with disabilities. A few commenters indicated these proposals improve the potential for D–SNPs to provide person-centered care and support enrollees to remain independent and manage their health and daily activities. A few commenters indicated the proposals provide States with greater D–SNP coordination and oversight opportunities.

A few commenters believed the proposals would tighten and clarify requirements for D–SNPs. A commenter indicated the proposals would help simplify D–SNP offerings, and another commenter noted support for the proposed rule's goal of strengthening consumer protections to ensure dually eligible individuals have access to accurate and accessible information about health plan choices and benefits. A few commenters believed the proposals would help engage enrollees in designing and participating in care. Another commenter indicated the proposals offer the potential for both administrative and clinical integration at the plan level.

A commenter encouraged CMS to couple implementation of the final rule with guardrails to mitigate against potential unintended consequences. Another commenter encouraged CMS to quickly adopt regulations that reflect stakeholder recommendations in light of the rapid growth of D–SNPs.

Several commenters expressed support for the package of D–SNP proposals as useful incremental steps toward furthering integrated care via D–SNPs. A commenter encouraged CMS to consider how steps taken now build towards a broader long-term vision for integrated care. Another commenter acknowledged that CMS did not want to be prescriptive but encouraged CMS to provide sufficient detail with regard to the array of D–SNP proposals when finalizing the rule given the recent growth in the D–SNP landscape.

Response: We appreciate the widespread support for our proposals. As discussed in the proposed rule (87 FR 1850), these proposals build on two recent MA/Part D rulemakings and our experiences with MMP policies. We believe this final rule will further the potential of D–SNPs to deliver person-centered integrated care—and ultimately better health outcomes and independence in the community—for dually eligible older adults, people with disabilities, and people with end stage renal disease.

As we discuss later in this section under specific proposals, we will provide technical assistance, monitor implementation of the finalized provisions, and consider future rulemaking as needed to address any identified areas of concern. For example, information from CMS audits will help us monitor the extent to which MA organizations are meeting the enrollee advisory committee requirements at § 422.107(f), and we may consider more prescriptive requirements, as needed, based on implementation experience.

We acknowledge the request for additional detail related to some of the D–SNP proposals. As we discuss in response to comments on specific

[12] Bipartisan Policy Center, Guaranteeing Integrated Care for Dual Eligible Individuals (2021) and A Pathway to Full Integration of Care for Medicare-Medicaid Beneficiaries (2020).

proposals later in this section, we aim to strike a balance between providing MA organizations with flexibility in implementing various finalized requirements versus being more prescriptive. We explain our rationale further in responses to comments, including related to requirements for enrollee advisory committees at § 422.107(e), SDOH questions in SNP HRAs at § 422.101(f)(1)(i), and limited carve-outs of Medicaid behavioral health services and long-term services and supports (LTSS) at § 422.107(g) and (h).

Comment: A number of commenters commended CMS for applying lessons learned from MMPs to D–SNPs and providing a long-term strategy for D–SNPs as an integrated plan option. A few commenters stated that the MMP demonstrations created a gold standard for integrated care and have given beneficiaries avenues for providing input on plan operations though beneficiary advisory committees; enhanced the beneficiary experience through integrated communications materials; scaled up person-centered care planning and care coordination including effectively combining medical and behavioral health benefits; and delivered a platform for incentivizing innovation and investment to improve quality of care for dually eligible individuals. Several commenters noted the achievements of particular States and MMPs in the FAI and expressed appreciation for the CMS goal of establishing a more permanent mechanism to sustain integrated programs beyond the demonstrations.

MACPAC expressed support for CMS for proposals to promote integration by applying features of the MMPs operating under the FAI to D–SNPs. MedPAC encouraged CMS to extend some of the proposals that promote integration to HIDE SNPs too. A few commenters acknowledged the role of nonmedical benefits in providing care to complex populations and expressed appreciation for flexibilities in payment and benefit design.

Response: We thank the commenters for the support for the proposals that incorporate many of the early lessons learned from the MMP experience into the broader MA program. We believe doing so will improve experiences for dually eligible individuals.

Comment: A few commenters expressed support for the work of the CMS Medicare-Medicaid Coordination Office (MMCO) to improve care for dually eligible individuals, address needs around integration of care, focus on social determinants of health, and promote equity, while another commenter noted appreciation for MMCO efforts to lower health care costs for beneficiaries, States, and Federal Government.

Response: We thank commenters for their support.

Comment: Several commenters noted that Federal support would be an important component to helping States implement the necessary changes and to facilitate further integration of D–SNPs. These commenters noted that State officials often struggle with competing priorities, limited Medicare knowledge, and limited staff capacity to develop and implement integrated care initiatives for dually eligible individuals relative to their other responsibilities. A few commenters acknowledged the wide range of technical assistance that CMS has provided to date to help navigate the complexities of the policy environment and expand State ability to integrate and encouraged CMS to continue to bolster these resources for States should the proposals in this rule become final. Other commenters recommended that States would need additional Federal funding to enhance State capacity and to further incentivize integration.

Response: We thank the commenters for this feedback and agree that States are an important partner in implementing many of the D–SNP proposals in this rule. We are committed to continue working closely with States to support their integration efforts and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center (see *https://integratedcareresourcecenter.com*).

Comment: A few commenters noted the importance of robust oversight to ensure that policies do not lead to higher spending without actually benefiting people with Medicare and supported the increased oversight of D–SNPs contained within the proposed rule. A commenter expressed concern as to whether there was sufficient demographic data, especially on disability and on social, racial, and economic status, or data on MA supplemental benefit spending, access, and eligibility for such oversight. Another commenter expressed concern that the Federal Government lacks the capacity to conduct adequate oversight without sharing responsibility with States.

Response: We thank the commenters for these comments. We agree that oversight is an important component of providing person-centered, high quality care and will continue to work with stakeholders to ensure integrated programs do just that. We will consider opportunities for improving the types and quality of available data necessary to support such oversight in the future. We address issues related to expenditure data on MA supplemental benefits as part of MLR reporting in section II.G of this final rule.

Comment: A few commenters supported the focus on the D–SNP model for deepening integration, pointing out the widespread availability and growing enrollment in D–SNPs and the ongoing investments by plans and States in supporting infrastructure. The commenter indicated the provisions included in the proposed rule were a logical alternative to other more radical integration proposals. A commenter specifically appreciated CMS's focus on the experience of D–SNP enrollees given the large number of enrollees in D–SNPs in certain States and the health care needs of these individuals.

Response: We thank the commenters for this feedback. As we discussed in the proposed rule at 87 FR 1888, the integrated care landscape has changed substantially over the last 10 years. Key changes include Congress making D–SNPs permanent, establishing new minimum integration standards, and directing the establishment of unified appeals and grievance procedures. Changes in MA policy have also created a level of benefit flexibility that did not previously exist outside of the capitated model demonstrations, with MA plans increasingly offering supplemental benefits that address social determinants of health and LTSS. These changes make D–SNPs an attractive vehicle for integration for dually eligible individuals.

Comment: A few commenters stated that the proposals do not go far enough to further integrated care. A commenter stated that the proposed changes do not address the main factors that determine long-term beneficiary satisfaction with integrated care, such as access to providers, easily understood marketing or other materials to help inform beneficiaries of their choices, and access to supplemental benefits. Another commenter stated that while the proposed policy changes promote integration in existing products, they do not necessarily increase the availability of integrated models or enrollment in integrated plans.

Response: We appreciate the feedback from these commenters. We believe several of our proposals address factors that determine beneficiary satisfaction—see, for example, our proposal at § 422.107(e) related to using specified integrated materials—but we appreciate that there remain many other

opportunities to improve experiences for dually eligible beneficiaries. We will consider whether there are additional opportunities to address these issues in the future.

Comment: A few commenters supported the overall effort to promote care integration for dually eligible individuals but expressed concern about the potential for increased administrative burden for State Medicaid agencies, disruptions in care for members, and other operational challenges. A commenter expressed concern that some of the proposals would significantly curtail States' ability to customize programs that meet the specific needs of their State programs and constituents. Another commenter noted that the proposals are likely to be most impactful for States that are relatively far along in their integrated care strategies and recommended CMS continue its efforts through the Medicare-Medicaid Coordination Office and the Integrated Care Resource Center to promote integration for States newer to this policy area. A commenter was concerned that the operational aspects of some of the provisions would disadvantage new entrants to the MA market, particularly those that target underserved populations. Another commenter emphasized that CMS has an opportunity to ensure States do not use the proposed changes to hinder new market entrants who may offer more and better service to beneficiaries.

Response: We thank the commenters for these comments and acknowledge the concerns they raise. It is important to note that none of the provisions in the proposed rule would impose new requirements on States; rather, States may choose whether or not to take advantage of any of the proposals finalized here. We are committed to continue working closely with States to support their integration efforts, regardless of how far along they are, and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center. While some proposals would impose new requirements of D–SNPs, we think on balance, the advantages of increasing the overall level of integration outweigh the potential downsides.

Comment: A commenter recommended allowing MA organizations to offer D–SNPs without holding a Medicaid contract either directly or between the parent company and the State Medicaid agency.

Response: We note that while State contracting policies may have prevented sponsors from offering D–SNPs in some markets, section 1859(f)(3)(D) of the Act requires a D–SNP to have a contract with the applicable State Medicaid agency. States are authorized to determine which D–SNPs they will contract with, as described in section 164 of the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–274), which amended section 1859(f) of the Act to add the requirement for D–SNPs to have a contract with the State.

Comment: A commenter recommended that CMS further define terms such as care coordination, person-centered care, and integrated care. This commenter believes further definition of these terms is important to gain trust among dually eligible individuals, especially those between the ages of 21 and 65 years old.

Response: An important theme of our proposals is to improve experiences for dually eligible beneficiaries who are enrolled in D–SNPs. As part of that, we aim to streamline and simplify operations, including the terminology we use. We appreciate these suggestions and will consider them for the future. We believe that the terms care coordination, person-centered care, and integrated care are sufficiently clear in this final rule that additional regulatory definitions are not necessary.

3. Enrollee Participation in Plan Governance (§ 422.107)

We believe managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.[13] By soliciting and responding to enrollee input, plans can better ensure that policies and procedures are responsive to the needs, preferences, and values of enrollees and their families and caregivers. One of the ways managed care plans can engage dually eligible individuals is by including enrollees in plan governance, such as establishing enrollee advisory committees and placing enrollees on governing boards. Engaging enrollees in these ways seeks to keep enrollee and caregiver voices front and center in plan operations and can help plans achieve high-quality, comprehensive, and coordinated care.[14] As described at 87 FR 1855 through 1856 of the proposed rule, Federal regulations for other programs, such as the Programs of All-Inclusive Care for the Elderly (PACE) and Medicaid managed care plans that cover LTSS include requirements for stakeholder engagement and committees, including input from beneficiaries.

As required by the three-way contracts between CMS, States, and MMPs, all MMPs established enrollee advisory committees. As described at 87 FR 1854 through 1855 of the proposed rule, these enrollee advisory committees provide a mechanism for MMPs to solicit feedback directly from enrollees, assisting MMPs in identifying and resolving emerging issues, and ensuring they meet the needs of dually eligible individuals.

We believe that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by D–SNPs and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals. Therefore, we proposed at § 422.107(f) that any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees to solicit direct input on enrollee experiences. We also proposed at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

We proposed to establish the new paragraph at § 422.107(f) under our authority at section 1856(b)(1) of the Act to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program and our authority at section 1857(e) of the Act to adopt other contract terms and conditions not inconsistent with Part C as the Secretary may find necessary and appropriate. We believe that a requirement for an MA organization offering one or more D–SNPs to establish one or more enrollee advisory committees is not inconsistent with either the Part C statute or administration of the MA program. While current law does not impose such a requirement, our experience with existing requirements for MMPs and PACE demonstrates that the use of

[13] Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners.* Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf.*

[14] Resources for Integrated Care and Community Catalyst, ''Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/Member_Engagement/Video/Listening_to_Voices_of_Dually_Eligible_Beneficiaries.*

advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face, as well as serving as a convenient mechanism to obtain enrollee input on plan policy and operational matters. Our experience also suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees. We believe the performance of all D–SNPs would benefit from this new requirement and that this requirement is therefore necessary and appropriate.

While we described the proposed advisory committee at § 422.107(f) as an enrollee advisory committee consistent with the use of the term ''enrollee'' in MA regulations, we noted that ''enrollee'' under the proposed § 422.107(f) requirement for D–SNPs has the same meaning as ''member'' under the § 438.110 requirement for Medicaid plans to have a member advisory committee when LTSS are covered under a Medicaid managed care plan's contract.

First, we proposed that the MA organization offering one or more D–SNP(s) in a State must have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. As proposed, an MA organization would be able to choose between establishing one single enrollee advisory committee for one or multiple D–SNPs in that State or by establishing more than one committee in that State to meet proposed § 422.107(f).

Second, we proposed that the advisory committee must have a reasonably representative sample of enrollees of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees. At 87 FR 1856 of the proposed rule, we explained that, by using the phrase ''representative sample'' in the regulation text, we intended that D–SNPs incorporate multiple characteristics of the total enrollee population of the D–SNP(s) served by the enrollee committee, including but not limited to geography and service area, and demographic characteristics. For MA organizations that offer separate D–SNPs serving full-benefit dually eligible individuals and partial-benefit dually eligible individuals in the same State, we explained that our proposal would provide flexibility for MA organizations to solicit enrollee input through one or more committees where separate committees might represent specific eligibility groups.

Finally, we proposed that the advisory committee must, at a minimum, solicit input on ways to improve access to covered services, coordination of services, and health equity among underserved populations, which is a CMS priority aligned with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021). Our proposal did not specify other responsibilities or obligations for the committee, but we encouraged D–SNPs to solicit input from enrollees on other topics would be part of the committee's responsibilities.

At 87 FR 1857 of the proposed rule, we described how our proposal would relate to the requirement at § 438.110 for Medicaid managed care plans that cover long-term services and supports and how some organizations may satisfy our proposed requirement at § 438.110 with the same advisory committee.

Citing our belief that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement, we did not propose Federal requirements as to the specific frequency, location, format, participant recruiting and training methods, or other parameters for these committees beyond certain minimum requirements. However, we solicited comments on whether we should include more prescriptive requirements on how D–SNPs select enrollee advisory committee participants, training processes on creating and running a successful committee, the committee responsibilities, additional committee topics, and whether we should limit the enrollee advisory committee proposed at § 422.107(f) to a subset of D–SNPs. We also solicited comments on whether our approach to allow MA organizations to meet the requirements in proposed §§ 422.107(f) and 438.110 through one enrollee advisory committee could dilute the § 438.110 requirement by detracting from the focus on LTSS enrollees. We noted that, if our proposal were finalized, we would update the CMS audit protocols for D–SNPs to request documentation of enrollee advisory committee meetings.

Comment: Numerous commenters expressed strong support for our proposal to require that an MA organization offering one or more D–SNP(s) in a State have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. Many of these commenters noted direct input from enrollees helps to improve plan quality, operations, and care coordination to better serve its enrollees and can help advance health equity among dually eligible individuals. A number of commenters stated that their support for our proposal was informed by their experience with enrollee advisory committees implemented by MMPs, Medicaid managed care plans, and D–SNPs. Numerous commenters suggested that engagement of enrollees representing the diversity of the dually eligible population in a State is essential to providing meaningful person-centered care and effectively coordinating and integrating care across Medicare and Medicaid services in a manner that reflects individual's needs and preferences. A commenter shared their experience implementing D–SNP enrollee advisory committees, noting these committees are a chance to build trust with enrollees, improve plan processes, address health equity barriers, and empower enrollees as active contributors and co-designers of programs and policies. Some commenters appreciated that our proposal builds on existing Federal regulations that require enrollee advisory processes among Medicaid LTSS managed care plans and PACE and similar requirements for MMPs, which would create fewer differences for State staff managing multiple integration efforts and preserve flexibility in the design of these committees. MACPAC expressed its support for the proposal and welcomes CMS modeling the structure after the MMP committees to include beneficiaries, families, and other caregivers. Some commenters viewed the proposed committee requirement as an opportunity for States to cross-pollinate committee input and activities across D–SNPs that operate in their State. Other commenters appreciated the proposed requirement for the committee to encompass a representative sample of D–SNP enrollees within a State and noted that, because of this requirement, plans constructing these committees would take efforts to recruit participants from the diverse backgrounds of their enrollees.

Response: We appreciate the widespread support we received for our proposal. These comments bolster our belief that the establishment and maintenance of an enrollee advisory

committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals. We agree that the requirement that D–SNPs include a reasonably representative sample of members will incentivize them to consider diversity when recruiting for their enrollee advisory committees.

Comment: A commenter applauded CMS's effort to create more mechanisms for enrollee input in plan operations and consult enrollees on issues related to health equity. But, this commenter believed requiring each SNP to establish and maintain a separate advisory committee could be redundant and duplicative with existing efforts. The commenter offered the example that, in many regions, coalitions or community groups already exist that can provide input on enrollee needs and stated that in some cases the existing coalitions or community groups are already prepared to inform plans about the challenges that impact their enrollees. This commenter recommended that CMS require all SNPs to have a mechanism to obtain diverse and representative enrollee input on plan policy and operations rather than requiring all D–SNPs to use the specific mechanism of enrollee advisory committees. Further, the commenter suggested that where community groups do not already exist, plans could then establish their own enrollee advisory committees.

Response: We thank the commenter for this perspective. We would like to take the opportunity to clarify that our proposal would not apply to all SNPs but MA organizations with one or more D–SNPs in a State. While C–SNPs and I–SNPs could benefit from enrollee advisory committees and the type of engagement described by the commenter, and we encourage them to do so, we are not requiring it at this time. Our experience with such committees has been concentrated on plans exclusively or mainly enrolling dually eligible individuals, so we have chosen to apply this requirement to D–SNPs. Based on the D–SNP experience with such committees, we may consider future rulemaking to consider such a requirement for C–SNPs and I–SNPs.

We recognize that coalitions and groups serving local communities can offer helpful perspectives to MA organizations and D–SNPs and our proposal does not preclude MA organizations and D–SNPs from engaging with other parties to gather feedback. But, our experience with existing requirements for MMPs and PACE demonstrates that the use of advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face, as well as serving as a convenient mechanism to obtain enrollee input on plan policy and operational matters. Our experience also suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees. We believe the performance of all D–SNPs would benefit from this new requirement, which is consistent with the existing requirement at § 438.110 for Medicaid plans to establish member advisory committees when those Medicaid managed care plans cover LTSS.

Comment: Several commenters requested technical assistance for MA organizations and D–SNPs to help establish the proposed enrollee advisory committees. A few of these commenters stated that establishing robust enrollee advisory committees can be challenging. A commenter emphasized that the existence of an advisory committee is not itself a demonstration of enrollee input, but that these committees must be intentionally designed, integrated into overall program structures to be considered true enrollee engagement, and have decision-making authority. Another commenter requested that CMS provide technical assistance and guidance documents and/or training to plans, States, and consumer advocates on effective and standardized practices for these committees. A commenter suggested CMS leverage two existing resources on the topic of consumer engagement in enrollee advisory committees as technical assistance for plans regarding how to build a meaningful advisory committee.[15]

Response: We welcome this feedback and agree that technical assistance to support the design and implementation of enrollee advisory committees is important. CMS's contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, and offered a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees in 2019.[16] In the proposed rule at 87 FR 1855, we outlined some of the best practices leading to successful enrollee advisory committees. We also noted in the proposed rule (87 FR 1888) that we intend to continue—focusing now on D–SNPs—many of the technical assistance and quality improvement activities that we initially developed for MMPs, including—

- Learning communities;
- Direct work with beneficiary advocates and other stakeholders;
- Targeted efforts to improve outcomes and reduce disparities; and
- Capacity building on topics like person centeredness, disability-competent care, dementia, and behavioral health.

We expect these topics to also include a focus on enrollee advisory committees.

Comment: We received numerous comments in favor of more prescriptive requirements and numerous comments in favor of a less prescriptive approach consistent with our proposal.

Among those in favor of more prescriptive requirements, numerous commenters requested that we provide clarification or further requirements on selection processes for enrollee advisory committees and what we consider to be a reasonably representative sample of the population enrolled in the D–SNP. Several commenters suggested that a reasonably representative sample should include enrollee characteristics such as race, ethnicity, language, disability status, sexual orientation and gender identity, receipt of LTSS or behavioral health services, geography and service area. A few commenters suggested that we establish percentage thresholds, such as a majority of committee participants are dually eligible individuals or a majority of participants are non-white or non-English speaking. A commenter recommended that enrollee advisory committees be composed of a majority of participants based on the proportional representation of enrollees with lived experiences and demographic identities, including disability, while other commenters requested we provide specific

[15] Community Catalyst, ''Meaningful Consumer Engagement: A Toolkit for Plans, Provider Groups and Communities,'' March 2014. Retrieved from *http://www.advancingstates.org/hcbs/article/meaningful-consumer-engagement-toolkit-plans-provider-groups-and-communities*; and Community Catalyst, ''Supporting Meaningful Engagement through Community Advisory Councils,'' August 2020. Retrieved from: *https://www.healthinnovation.org/resources/publications/supporting-meaningful-engagement-through-community-advisory-councils.*

[16] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/article/member-engagement/.*

parameters on how D–SNPs might meet the definition of ''representative sample''. Some commenters requested that we specify a minimum number of participants for the enrollee advisory committees. A commenter recommended that CMS establish a threshold for volume of D–SNP enrollees that a single committee could represent, suggesting one committee per D–SNP or per a certain number of D–SNP enrollees across plans (for example, 20,000). This commenter also recommended that D–SNPs be required to notify eligible enrollees of the opportunity to participate. Another commenter suggested we relax the representative sample requirement, as it is difficult for D–SNPs to engage all populations enrolled to include representation on advisory committees.

Another commenter requested that CMS direct MA organizations to work with stakeholders, such as patient advocacy groups, to ensure enrollee advisory committees include a diverse and comprehensive patient population. MACPAC expressed that these committees should be developed by plans in partnership with advocates and should be representative of the people served by integrated programs. A few commenters noted that CMS should require D–SNPs to allow caregivers, personal care attendants, interpreters, and others to attend to help enrollees participate.

In making its case for more prescriptive requirements, a commenter remarked that an analysis of MMP advisory committees indicates that, despite requirements in most States that committee membership reflects the diversity of the member body, the lack of guidance on what diversity means or how to properly recruit leads to under-representation of minority enrollees in committees. According to the commenter, not defining ''reasonable sample'' of individuals enrolled in D–SNPs increases the risk that the committee does not adequately represent the D–SNP enrollees.

Response: We appreciate the commenters' suggestions for additional specificity in requirements for establishing enrollee advisory committees for MA organizations with one or more D–SNPs in a State. Given the variation in State Medicaid program, D–SNPs, and dually eligible populations across States and localities and the existence of enrollee advisory committees established under § 438.110, we continue to believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement.

We appreciate comments regarding the need for more prescriptive requirements with respect to enrollee advisory committee diversity, and the need to more specifically define a reasonable sample of D–SNP enrollment such that committee representation is an accurate reflection of overall enrollment. We recognize that a key finding from the 2019 report ''The Role of Consumer Advisory Councils in the Financial Alignment Initiative'' [17] was the need for improved diversity of enrollee advisory committee participation. The first annual report for the Massachusetts Financial Alignment Initiative demonstration found that attracting and retaining diverse stakeholder participation in the Implementation Council was a challenge.[18] The second annual report indicated the Implementation Council was able to recruit additional members, and one Implementation Council member noted that ''the resulting diversity was both exciting and challenging''.[19] While we are choosing to be nonprescriptive in how a reasonable sample is defined for the purposes of our new requirement, we may consider more prescriptive requirements based on information regarding how MA organizations implement committees and comply with the requirement that the D–SNP enrollee committees be reasonably representative of the enrolled population. Future technical assistance will include promising practices for how plans can build a diverse committee membership.

Comment: We received some comments from organizations requesting that we specify how often the enrollee advisory committees must meet. A few of these commenters encouraged CMS to establish minimum frequency requirements but did not specify a meeting interval. Several commenters recommended that we require enrollee advisory committees to meet at least twice per year, and a commenter suggested quarterly convenings. A few of these commenters expressed concern that, without a minimum required frequency, plans would opt for annual meetings, which the commenters indicated would have limited value.

A few commenters encouraged CMS to set training requirements for MA organizations and D–SNPs as they establish these committees. A commenter emphasized that CMS require D–SNPs to establish a process to train D–SNP staff on collecting and incorporating advisory committee feedback into plan operations and informing participants how enrollee feedback was used. We also received a comment that States should be given the authority to specify and require training components as part of their contracting with plans.

Some commenters encouraged CMS to provide more specifics related to training for enrollee advisory committee participants. A few of these commenters recommended requirements to ensure MA organizations educate enrollee advisory committee participants about the responsibilities of these committees and ways to meaningfully engage in them, including providing an understanding of D–SNP program design and organizational structure. A commenter suggested that CMS include a requirement that the enrollee advisory committee receives training on key health and health care disparity concerns that affect the population served by the D–SNP and a robust module be provided on disability inclusion in health care, emphasizing intersectional identities. This commenter also suggested that D–SNPs provide the committee basic information about the right to request reasonable accommodations and policy modifications, an overview of the D–SNPs' transparency and accountability mechanisms, and local and State agencies and commissions with overlapping responsibilities and interests. A few of the commenters suggested that CMS create standards for training processes but did not provide further details.

A few commenters suggested that CMS require enrollee advisory committees to incorporate other parameters. A commenter recommended that enrollees, not State authorities, should lead the committee process. Another commenter stated that CMS should consider other required feedback mechanisms for enrollee input beyond the proposed committee structure, which—in their view—could have a limited number of participants or may not include those who have voiced concerns about the plan. Another commenter suggested that CMS require MA organizations to implement best

[17] Center for Consumer Engagement in Health Innovation, ''An Exploration of Consumer Advisory Councils within Medicare-Medicaid Plans Participating in the Financial Alignment Initiative'', 2019, Retrieved from: *https://www.healthinnovation.org/resources/publications/an-exploration-of-consumer-advisory-councils-within-medicare-medicaid-plans.*

[18] RTI, ''Financial Alignment Initiative Annual Report: One Care: MassHealth Plus Medicare, First Annual Report,'' September 2016 (updated July 2017). Retrieved from: *https://innovation.cms.gov/files/reports/fai-ma-firstevalrpt.pdf.*

[19] RTI, ''Financial Alignment Initiative: Massachusetts One Care Second Annual Report,'' April 2019. Retrieved from *https://innovation.cms.gov/files/reports/fai-ma-secondevalrpt.pdf.*

practices to ensure enrollee advisory committee participant retention and equity.

A few commenters urged CMS to issue additional sub-regulatory guidance concerning its expectations of MA organizations and D–SNPs in establishing these enrollee advisory committees.

Some commenters suggested specific topics the committee should be required to focus on beyond the health equity topic included in the proposed rule. A few commenters recommended that the committees focus on concerns and priorities of the enrollees themselves. A commenter supported additional topics be shared with committee participants for their input but did not name any particular topics. Another commenter did not specify any additional topics but suggested that the D–SNPs provide information to alert the enrollee advisory committee participants of the scope of potential topics, such as through a non-exhaustive list of topics other advisory committees have tackled. A few additional commenters identified specific topics for consideration, such as medication adherence, D–SNP collection of self-identified functional limitation data, and addition of self-identified functional limitation data fields to electronic patient records.

Response: We appreciate the commenters' suggestions for additional specificity in requirements for establishing enrollee advisory committees. We continue to believe that giving D–SNPs flexibility in structuring the enrollee advisory committees will permit D–SNPs—and the enrollees participating on the advisory committees—to tailor these committees based on the local needs of enrollees. As we stated in the proposed rule, our experience with MMPs establishing and maintaining enrollee advisory committees demonstrates that these plans have found the committees useful and carefully consider feedback provided by enrollees to inform plan decisions without prescriptive Federal requirements for the committees. We expect the evolution and adoption of telecommunications technology, including as experienced during the COVID–19 public health emergency, will mean that the most effective modalities for enrollee input may change over time. Therefore, we are not finalizing any additional Federal requirements as to the specific frequency, location, format, participant recruiting and training methods, or other parameters for these committees beyond certain minimum requirements; however, we may consider more prescriptive requirements in future rulemaking based on D–SNP experience with enrollee advisory committees.

Comment: Numerous commenters emphasized the importance for transparency of these enrollee advisory committees and ensuring D–SNPs are held accountable for adhering to established requirements. Several commenters suggested that MA organizations create a feedback loop for advisory committees to see how their feedback is being considered and implemented and to share this information with enrollee advisory committee participants. A few commenters welcomed information on how CMS would evaluate the effectiveness of the enrollee advisory committees, including any expected measurable outcomes, to better understand how well the committees are achieving policy goals. Another commenter requested that CMS consider whether there may be additional Federal and State benefits to compiling the findings of these enrollee advisory committees since this information may help inform future policy duration for not only MA plans and SNPs but also for the original Medicare FFS program.

Response: We appreciate the request for monitoring of enrollee advisory committees against the requirements outlined at § 422.107(f) and the interest in information gathered through these convenings. We are not requiring that MA organizations publicly distribute enrollee advisory committee meeting agendas or materials since these committees will be addressing challenging topics related to plans and their enrollees, including potentially market-sensitive information related to potential changes in future plan benefits. We are concerned that requiring plans to make these agendas and materials publicly available could interfere with committee effectiveness. We noted in the proposed rule that, if our proposal were finalized, we would update the CMS audit protocols for D–SNPs to request documentation of enrollee advisory committee meetings. Information from CMS audits will help us monitor the extent to which MA organizations are meeting the enrollee advisory committee requirements at § 422.107(f), and we may consider more prescriptive requirements, as needed, based on implementation experience.

Comment: Numerous commenters supported the flexibility CMS offered in the structure of the proposed enrollee advisory committees and urged CMS to require a less prescriptive approach to the enrollee advisory committees, consistent with the proposed rule. Many of these commenters favored a minimum set of requirements to give D–SNPs the flexibility to implement and manage enrollee advisory committees that best meet the needs of the local population and obtain meaningful input. Several commenters stated that the design flexibilities encourage the development of enrollee advisory committees to best reflect the different types of D–SNPs (that is, fully integrated dual eligible (FIDE) SNPs, highly integrated dual eligible (HIDE) SNPs, coordination-only D–SNPs [20]) currently in place and the complexity of the dually eligible populations enrolled, which can differ from one locale to another. Some commenters noted that this flexibility would allow plans that currently offer D–SNPs in multiple States to build a foundation for an advisory committee that can be modeled and then refined to address specific needs of populations represented in each committee. Several commenters urged CMS not to be prescriptive with enrollee advisory committee requirements, especially for plans that already have such committees in place. These commenters emphasized that flexible enrollee advisory committee requirements would allow plans to build on experience and existing enrollee feedback approaches to best reflect the nuance and complexity of the D–SNP plans offered and populations served by those plans. Other commenters noted that this flexibility allows MA organizations already implementing such committees to continue existing operations without major changes, and the flexibility would allow plans to avoid overlapping or duplicative requirements from CMS and States as well as avoid beneficiary confusion. In supporting this perspective, a commenter explained that its experience offering FIDE SNPs, HIDE SNPs, and coordination-only D–SNPs across multiple States suggested wide variation in the specific benefits covered and populations served. Another commenter expressed concern that an overly prescriptive approach would reduce the flexibility for innovation and could stifle some of the positive strides already underway among managed care plans.

Response: We thank the commenters for their perspectives. Based on our experience with enrollee advisory committees operated by MMPs and PACE, we believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for the enrollee advisory committees.

[20] Coordination-only D–SNPs are D–SNPs that neither meet the FIDE SNP nor HIDE SNP definitions at § 422.2.

Permitting flexibility for the enrollee advisory committees gives MA organizations—and enrollees themselves—more opportunity to establish committees that best meet the needs of enrollees.

State Medicaid agencies have broad authority to include more prescriptive parameters for enrollee advisory committees in their contracts with D–SNPs and could adopt some of the commenters' suggestions appropriate to their State through these State Medicaid agency contracts. As discussed in the proposed rule at 87 FR 1857, some State Medicaid agencies already do this in applying § 438.110.

Though we are choosing to be nonprescriptive on meeting frequency, location, format, enrollee recruitment, training, and other parameters, we encourage D–SNPs to adopt identified best practices [21] to ensure advisory committee meetings are accessible to all enrollees, including but not limited to enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access technology and broadband. We note that compliance with Federal law related to accessibility and effective communications for persons with disabilities is a requirement under other statutes such as Section 504 of the Rehabilitation Act. We also clarify that the enrollee advisory committees are not meant to preclude MA organizations and D–SNPs from gathering enrollee feedback through other means. As we discussed at 87 FR 1856, our experience with existing requirements for MMPs and PACE suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees.

Comment: Some commenters requested that CMS clarify what documentation we will request as part of CMS audit protocols with respect to enrollee advisory committees. Other commenters suggested we audit enrollee advisory committees on the accuracy of committee representation of the D–SNP enrollee membership, meeting frequency and committee feedback to the D–SNP.

[21] Resources for Integrated Care and Community Catalyst, ''Engaging Members in Plan Governance'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/article/member-engagement/.*

Response: Information requested as part of the CMS audit protocols may be similar to that reported by MMPs as part of the reporting requirement (for example, dates of meetings held, number of enrollees invited, number of enrollees in attendance). As described in section IV.B.1.b., prior to implementation of new audit protocols (under OMB control number 0938–1395; CMS–10717), we will make them available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices.

Comment: Several commenters questioned whether D–SNPs could delegate the facilitation or operation of enrollee advisory committees to first tier, downstream, or related entities.

Response: There is nothing in rule that precludes a D–SNP from delegating the facilitation or operation of an enrollee advisory committee to a first tier, downstream, or related entity. Notwithstanding any relationship(s) that the D–SNP has with first tier, downstream and related entities, the MA organization maintains the ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, per § 422.504(i). All requirements with respect to the enrollee advisory committee are still applicable in the event a D–SNP delegates facilitation or operation of the enrollee advisory committee.

Comment: In addition to D–SNP enrollee advisory committees, some commenters recommended CMS require States to create centralized, cross-plan advisory councils, similar to the implementation councils currently in place for the Massachusetts and Rhode Island demonstrations under FAI. Commenters suggested these councils be comprised of majority of D–SNP enrollees and their caregivers, and expressed that such councils could provide additional transparency and insight into D–SNP policy and operations. A commenter suggested CMS provide Federal funding for these State-level advisory councils, and another commenter suggested an implementation council was best positioned to liaise and collaborate with other similar health services and LTSS/HCBS (home and community-based services) county and State-level committees including *Olmstead* committees, Money Follows the Person advisory committees, and Medicaid advisory committees.

Response: While we acknowledge the utility of a centralized advisory council, and commend the important work of the Massachusetts One Care Implementation Council in particular, we defer to States to decide whether to implement broader advisory councils in order to solicit feedback more broadly on their Medicaid managed care programs and the D–SNPs that operate in the State.

Comment: A commenter opposed the approach of allowing MA organizations to meet the requirements proposed in §§ 422.107(f) and 438.110 through one enrollee advisory committee, acknowledging that, although there is overlap in the enrollees served, there are important distinctions in the populations and topics relevant for each stakeholder group.

Response: While we appreciate the commenter's perspective that there are important distinctions in the populations served, and that there may be distinct topics for each group, there may also be instances in which populations align and therefore separate enrollee advisory councils may be duplicative. We believe the best approach is to be nonprescriptive and allow one enrollee advisory committee to satisfy both requirements in the instances in which the minimum requirements for §§ 422.107(f) and 438.110 are both met. States may choose to apply distinct requirements via their State Medicaid agency contracts and their Medicaid managed care contracts, such that plans would need distinct enrollee advisory committees for different plan populations.

Comment: Many commenters suggested we delay the implementation of the enrollee advisory committee provision to contract year 2024 or suggested a phased-in approach that would require FIDE and HIDE SNPs to implement the enrollee advisory committees starting in contract year 2023, with less integrated D–SNPs implementing in contract year 2024. Commenters indicated the need for additional time to develop outreach strategies, coordinate with States, and develop reasonable representation recruitment strategies. A commenter noted D–SNPs will need more than a few months to ensure membership represents the different enrollee perspectives impacted by access, infrastructure, clinical needs, economic status, and prevalence of social supports.

Response: While we acknowledge commenters concerns around potential operational challenges to establishing and convening an enrollee advisory committee, we are nonprescriptive on meeting committee frequency, location, format, participant recruitment and training methods. For this reason, we do

not believe a contract year 2023 implementation timeframe is unreasonable. Given the implementation timing of this rule, D–SNPs will have approximately 6 months prior to the effective date of January 1, 2023, to develop an enrollee advisory committee, and we are nonprescriptive regarding when in calendar year 2023 the committee must meet, as well as the number of meetings and meeting frequency. Further, the regulation permits use of one committee per State, allowing for D–SNPs to start with a single committee and develop more nuanced committees over time. Additionally, while we have committed to providing technical assistance to D–SNPs in this area, a number of resources on establishing meaningful enrollee advisory committees are currently available via the Resources for Integrated Care.[22]

Comment: Numerous commenters requested clarification on how D–SNPs could reimburse enrollee advisory committee members for their time and expertise, and suggested D–SNPs be able to offer stipends, transportation or transportation reimbursement for in-person meetings, and food and drink.

Response: We acknowledge the advantages of reimbursing enrollee advisory committee participants for their time and expertise, and prior technical assistance in this area [23] has cited incentives as a best practice to recruit and retain enrollee advisory committee members. We clarify that enrollee participation in an advisory committee is neither a marketing activity nor a personal enrollee health-related activity that would fall under § 422.134, so the authorities and limits that are specific to those activities under MA regulations would not apply. However, MA organizations are prohibited from providing cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise by sections 1851 and 1854 of the Act. D–SNPs should ensure that any incentives be structured to avoid an inadvertent impact on enrollee eligibility for public benefits. In addition, the provision of stipends, transportation reimbursement, or anything else of value to D–SNP enrollees serving on the enrollee advisory committee potentially implicates the Federal Anti-kickback Statute (AKS), found in section 1128B(b) of the Act. Whether any particular arrangement violates the AKS would be based on the specific facts and circumstances. D–SNPs must ensure that the provision of reimbursement to these members complies with the AKS and other applicable law. We will provide future technical assistance to D–SNPs on this issue to help avoid unintended consequences related to plan compliance or enrollee eligibility for public programs.

Comment: A number of commenters expressed concerns about operationalizing an enrollee advisory council for a D–SNP that has low enrollment. Commenters cited concerns about D–SNPs' ability to meet the reasonably representative sample if overall plan enrollment is too small, particularly for a newly established plan or a plan operating in a rural service area. These commenters suggested CMS either set a minimum enrollment threshold or allow for advisory committees to cross geographies (for example, via multi-State consumer advisory councils). A few commenters recommended we set the minimum D–SNP enrollment threshold at 1,000 enrollees for the establishment of enrollee advisory committees. A commenter requested we consider exempting new plans from this requirement, while another recommended small plans be able to meet the requirement via focus groups, surveys, or other methods.

Response: While we appreciate the commenters' recommendations with respect to low-enrollment D–SNPs and the challenges low D–SNP enrollment might present in operationalizing a consumer advisory committee, we do not agree that the reasons cited create a significant barrier for MA organizations to meet the new requirement. First, we would like to clarify that an MA organization offering one or more D–SNP(s) in a State must have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. As proposed and finalized here, an MA organization would be able to choose between establishing a single enrollee advisory committee for one or more D–SNPs in that State or by establishing multiple committees in that State to comply with § 422.107(f). Thus, in situations where an MA organization operates more than one D–SNP in a State, the MA organization can, unless State Medicaid agency contracts dictate otherwise, establish one or more committees that encompass multiple D–SNPs in a State, which should help to address concerns related to low enrollment in any given D–SNP. Second, a number of MMPs that participated in FAI had low enrollment (that is, fewer than the suggested 1,000 enrollee threshold) and were able to operationalize meaningful enrollee advisory committees. Third, we are nonprescriptive in this requirement regarding how an MA organization recruits committee membership, the timing, frequency or number of advisory meetings an MA organization must conduct in a calendar year, and the meeting's format (for example, in person or virtual). The reasonably representative requirement is also sufficiently flexible that small plans can meet the standard. With this level of flexibility, we believe it is reasonable for D–SNPs that may have low enrollment to meet the requirements finalized at § 422.107(f).

Comment: Some commenters asked us to clarify or confirm whether D–SNPs have the flexibility to convene their advisory councils virtually. A commenter noted current use of digital platforms, while other commenters suggested virtual meetings may encourage greater enrollee participation. A few commenters specifically welcomed the flexibility in committee format (that is, in-person vs. virtual). A commenter explained that while in-person meetings remain the gold-standard for engagement, providing flexibility in how a D–SNP advisory committee engages with enrollees would help maximize enrollee engagement and provide flexibility for the D–SNP to evolve its processes as new effective methods become available.

Response: We are not proposing Federal requirements regarding the means by which enrollee advisory committees or committee meetings convene (either in-person or virtually). We confirm that MA organizations can meet the minimum requirements at § 422.107(f) by convening meetings virtually, provided they are not restricted from doing so via their State Medicaid agency contract. However, we reiterate our encouragement of D–SNPs to adopt identified best practices to ensure advisory committee meetings are accessible to all enrollees, including where lack of meaningful access to internet technology and broadband may limit involvement.

Comment: In the proposed rule, we solicited comments on whether we should limit enrollee advisory committees to a subset of D–SNPs. A few commenters agreed that the new requirement should apply to all D–SNPs, noting it to be the most comprehensive approach to soliciting feedback from dually eligible enrollees,

[22] Resources for Integrated Care ''Engaging Members in Plan Governance'', Retrieved From: *https://www.resourcesforintegratedcare.com/article/member-engagement/*.

[23] Resources for Integrated Care ''Engaging Members in Plan Governance'', Retrieved From: *https://www.resourcesforintegratedcare.com/article/member-engagement/*.

while acknowledging some D–SNPs may already have enrollee advisory councils that meet the new requirement. A commenter noted that while it had encouraged applying enrollee advisory committees to FIDE SNPs in the past, it also supported applying this approach more broadly to all D–SNPs.

Response: We appreciate the comments of support and we agree that applying an enrollee advisory committee requirement to D–SNPs broadly, rather than a subset, is the better mechanism to solicit feedback directly from enrollees and assist D–SNPs in identifying and resolving emerging issues. We believe applying this requirement to all D–SNPs, including those with a low level of integration, is the best approach to elevate the voice of dually eligible enrollees across a wider array of States and circumstances.

Comment: To increase transparency, oversight, and accountability, a few commenters urged State Medicaid agency participation in D–SNP enrollee advisory councils, or to give States access to the proceedings and recommendations of the committees on at least a quarterly basis. In contrast, a commenter suggested the inclusion of State participation on enrollee advisory councils would add unnecessary complexity.

Response: Nothing in the proposed rule precludes State Medicaid agencies from requiring, via the State Medicaid agency contracts required by § 422.107, D–SNPs to include State representatives in their enrollee advisory council meetings. Additionally, through these State Medicaid agency contracts, States could require D–SNPs to provide additional reporting on D–SNP advisory councils as a means for additional transparency, accountability, and oversight.

Comment: A few commenters suggested CMS allow MA organizations to establish enrollee advisory committees on a regional or multi-State basis, to overcome barriers to enrollee participation or when D–SNP enrollment is small in any single State. A commenter suggested the MA–PD's enrollee advisory committee within a State include enrollee representatives of the plans' other Medicare products as another means to encourage enrollee participation, while another requested to include Medicaid-only participants on the advisory committee to meet the existing Medicaid managed care advisory requirement at § 438.110.

Response: Due to the variations in State Medicaid agency contracts and Medicaid, we believe there is value in keeping enrollee advisory councils specific to a State. This offers operational simplicity to MA organizations to meet any State-specific advisory committee requirements and would improve the effectiveness of an enrollee advisory committee without combining committee membership across States, where services, eligibility, and geography could vary greatly. While we intend this new requirement to generate feedback based on the unique experience of dually eligible enrollees via a D–SNP enrollee advisory committee, we recognize that committees may not always be made up solely of dually eligible enrollees, as organizations can use a single advisory committee to meet the Medicaid managed care advisory committee requirement at § 438.110. However, we do not agree that the enrollee advisory committee should include representatives from Medicare products that do not focus on dually eligible enrollees. In meeting the requirement proposed at § 422.107(f), there is nothing precluding MA organizations from establishing sub-committee arrangements to established enrollee advisory committees. Also, the proposed requirement does not preclude non-SNP MA plans from establishing separate enrollee advisory committees.

Comment: Many commenters indicated that the minimum of a single Statewide enrollee advisory committee across potentially multiple D–SNP products was an insufficient approach in larger States, where D–SNPs may have very large enrollment as well as geographically and demographically diverse service areas. Commenters noted that a combined enrollee advisory council in a large State would dilute the value of the committee. A commenter suggested CMS require each D–SNP to establish its own committee, and a few commenters requested flexibility for States to further direct committee geographic scope, composition, and other factors beyond the Federal minimum requirements, including the ability to require multiple committees for specific enrollee populations. Several other commenters asked CMS to clarify whether enrollee advisory committees need to be at the plan benefit package (PBP) level. Finally, a commenter expressed that even within a State and D–SNP parent organization, many D–SNPs have similar plan names and cover different benefits, which could lead to potential enrollee confusion if an advisory committee is established Statewide across D–SNP products.

Response: The new requirement established at proposed § 422.107(f) does not preclude States from using their State Medicaid agency contracts (as required by § 422.107) to impose more prescriptive requirements for D–SNP enrollee advisory committees based on D–SNP enrollment, service area geography, or any other characteristic. The new proposal does not require D–SNPs to implement enrollee advisory committees at the PBP level, although they could choose to do so. States could also require each D–SNP to develop its own committee, either at the contract or the PBP level. Additionally, organizations that operate multiple D–SNPs in a State could elect to establish and maintain multiple enrollee advisory committees that best represent their eligibility populations (for example, full- or partial-benefit dually eligible beneficiaries) and/or service areas. We believe this regulation sets a floor from which States and D–SNPs may work to craft enrollee advisory committees that best meet local population and plan needs without committee duplication or significant disruption of current enrollee advisory committee operations, as required either by States or § 438.110.

Comment: Many commenters questioned whether D–SNPs could use existing plan enrollee advisory committees—either FIDE SNP or committees representing Medicaid managed care plans that cover long term services and supports—to meet the new proposed requirement at § 422.107(f). A few commenters asked us to clarify that one enrollee advisory committee could be used to meet the new requirements in §§ 422.107(f) and 438.110, noting that competing advisory committees would be inefficient. Another commenter requested we provide clarity on how the proposal should be implemented with respect to LTSS and non-LTSS enrollee participants and corresponding council topics. Other commenters recommended the use of subcommittees (either D–SNP enrollee advisory committees specific to MLTSS or MLTSS advisory committee with a subcommittee specific to dually eligible enrollees) as a potential means to solicit more precise feedback on unique plan subpopulations.

Response: We acknowledge some D–SNPs, or their affiliated Medicaid managed care plans covering LTSS, are currently operating enrollee advisory committees to meet existing State requirements; these existing committees may satisfy the requirements at § 422.107(f). As we noted in the proposed rule, our proposal at § 422.107(f) would permit an organization that operates a D–SNP that is affiliated with a Medicaid managed care plan to use one enrollee advisory committee to meet both the requirement under § 438.110 and the requirement

proposed at § 422.107(f), when all the criteria in both regulations are met. However, a State may limit the ability of a D–SNP to use one committee to meet both regulatory requirements. Finally, nothing in our proposed requirement would preclude the use of subcommittees with respect to unique D–SNP subpopulations. As discussed earlier in this section, we are nonprescriptive on topics (for example, with respect to LTSS) covered by enrollee advisory committees so long as the minimum topics specified in the regulation (ways to improve access to covered services, coordination of services, and health equity for underserved populations) are addressed; however, we encourage D–SNPs and their advisory committees to choose topics most relevant to the populations served.

Comment: Numerous commenters requested we encourage or require D–SNPs to operate their enrollee advisory committees with accessibility, accommodations, and communications access in mind for enrollees with disabilities, as well as enrollees with limited literacy, limited digital literacy, lack of meaningful access to technology and broadband and limited English proficiency. Other commenters recommended CMS require D–SNPs provide interpretation and accommodation for individuals with hearing and vision disabilities and impairments. Another commenter recommended CMS require D–SNPs to conduct enrollee advisory committee meetings in the preferred language of the region/county, when that region's primary language preference is not English. A commenter noted the need for committee meeting materials in alternate formats, while another commenter urged CMS to require D–SNPs to provide accommodations to committee enrollees who lack transportation or access to the technology necessary to facilitate robust virtual participation. Finally, a commenter recommended that CMS provide parameters regarding the importance of D–SNPs facilitating access to enrollee advisory committees via training, recruitment, and location and timing of meetings that reflect the community and population to create a process that allows enrollees to meaningfully participate in the committee.

Response: We agree with the commenters that it is vitally important for MA organizations to facilitate meaningful enrollee access to their enrollee advisory committees through accommodations for their enrollees' needs in order to achieve a representative sample of enrollee perspectives and meaningful feedback from the enrollee advisory committees. Although we are choosing to be nonprescriptive on meeting frequency, location, format, enrollee recruitment and training methods, and other parameters, we encourage D–SNPs to adopt identified best practices to ensure advisory committee meetings are accessible for all enrollees. Ensuring that the enrollee advisory committee has a reasonably representative sample of the covered population should include taking steps to ensure access for enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access technology and broadband, particularly to the extent that these considerations are also relevant to improving access to covered services and health equity. Where D–SNPs serve enrollees with disabilities, limited literacy or limited English proficiency, we expect those characteristics to be reflected in the D–SNP's enrollee advisory committee membership. D–SNPs must comply with any applicable civil rights law. We note that existing Federal civil rights authorities such as Section 504 of the Rehabilitation Act of 1973, HHS' implementing regulation at 45 CFR part 84, and Title VI of the Civil Rights Act of 1964 and the implementing regulation at 45 CFR part 80 would likely apply to an MA organization's administrative functions, such as enrollee advisory committees. We encourage D–SNPs to also consider virtual accessibility and transportation accessibility for in person meetings for their enrollee committee membership.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed requirement for D–SNPs to establish and maintain enrollee advisory committees at § 422.107(f).

4. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of the Act requires each SNP to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessments conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan. We codified this requirement at § 422.101(f)(1)(i) as a required component of the D–SNP's MOC. In practice, we allow each SNP to develop its own HRA, as long as it meets the statutory and regulatory requirements.[24] In the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (86 FR 5864) (hereinafter referred to as the January 2021 final rule), we noted that integrated D–SNPs (by which we mean D–SNPs or their affiliates under the same parent organization also receiving capitation for Medicaid services) may combine their Medicare-required HRA with a State Medicaid-required HRA so long as the applicable requirements for the HRA under § 422.101(f) are met, to reduce assessment burden (86 FR 5879).

Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[25] This is particularly true for food insecurity, housing instability, and access to transportation. As summarized in our proposal rule at 87 FR 1858, CMS in recent years has addressed social risk through the identification and standardization of screening for risk factors, including finalizing several standardized patient assessment data requirements for post-acute care providers[26] and testing the Accountable

[24] In the CY 2016 Call Letter (an attachment to the Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies) released on April 6, 2015, CMS encouraged SNPs to adopt the components in the CDC's ''A Framework for Patient-Centered Health Risk Assessments'' tool but did not mandate their use. Specifically, CMS encouraged the use of elements that identify the medical, functional, cognitive, psychosocial and mental health care needs of enrollees.

[25] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/*.

[26] See the ''Medicare and Medicaid Programs: CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements'' final rule (84 FR 39151 through 39161) as an example. In the interim final rule with comment period (IFC) ''Medicare and Medicaid Programs, Basic Health Program and Exchanges; 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 27550 through 27629), CMS delayed the compliance dates for these

Health Communities (AHC) model under section 1115A of the Social Security Act. The AHC model tests whether systematically screening for health-related social needs and referrals to community-based organizations will improve health care utilization and reduce costs, and includes a CMS Innovation Center-developed AHC Health-Related Social Needs (HRSN) Screening Tool.[27]

As discussed in the proposed rule at 87 FR 1858 through 1859, many dually eligible individuals contend with multiple social risk factors such as food insecurity, homelessness, lack of access to transportation, and low levels of health literacy.[28] We posited that requiring SNPs to include standardized questions about social risk factors would be appropriate in light of the impact these factors may have on health care and outcomes for the enrollees in these plans and that access to this information would better enable SNPs to design and implement effective models of care.

We proposed to amend § 422.101(f)(1)(i) to require that all SNPs (chronic condition special needs plans, D–SNPs, and institutional special needs plans) include one or more standardized questions on the topics of housing stability, food security, and access to transportation as part of their HRAs. We noted that these questions would help SNPs gather the necessary information to conduct comprehensive risk assessments of each individual's physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) and would inform the development and implementation of each enrollee's comprehensive individualized plan of care as required at § 422.101(f)(1)(ii). Rather than include the specific questions in regulation text, we proposed that the questions be specified in sub-regulatory guidance. This would afford us some flexibility to modify questions to maintain consistency with standardized questions that are developed for other programs while still providing MA organizations with clear requirements; we expressed our intent to provide ample notice to MA organizations of any changes in the questions over time. As discussed in the proposed rule, SNPs would comply with the new requirement added to § 422.101(f) by including in their HRAs the standardized questions on these topics that we would specify in sub-regulatory guidance. We described in the proposed rule our intent to, at a minimum, align selected questions with the Social Determinants of Health (SDOH) Assessment data element [29] established as part of the United States Core Data for Interoperability Standard (USCDI) v2, when finalized and where applicable.

While we proposed that the regulation text specify that the wording of individual questions would be established through sub-regulatory guidance, we provided examples in the proposed rule of the questions on these topics used in other Medicare contexts to provide better context on the proposed requirement and to solicit public comment. These examples included the transportation question in the post-acute care patient/resident instruments [30] and the housing and food insecurity questions from the AHC Model HRSN Screening Tool.[31]

As discussed in the proposed rule at 87 FR 1859, our proposal would result in SNPs having a more complete picture for each enrollee of the risk factors that may inhibit accessing care and achieving optimal health outcomes and independence. We believe that these questions are sufficiently related to and provide information on enrollees' physical, psychosocial, and functional needs to be appropriate to include the HRAs. Having knowledge of this information for each enrollee would better equip MA organizations to develop an effective plan of care for each enrollee that identifies goals and objectives as well as specific services and benefits to be provided. Our proposal would also equip SNPs with person-level information that would help them better connect enrollees to covered services and to social service organizations and public programs that can help resolve housing instability, food insecurity, transportation needs, or other challenges. Coordinating care along these lines is consistent with the obligations under § 422.112(b)(3) for MA organizations that offer coordinated care plans.

We did not propose that SNPs be accountable for resolving all risks identified in these assessment questions, but § 422.101(f)(1)(i) requires that the results from the initial and annual HRAs be addressed in the individualized care plan. As explained in the proposed rule at 87 FR 1859, results of the HRAs would not require SNPs to provide housing or food insecurity supports, but having the results means that SNPs would need to consult with enrollees about their unmet social needs, which may include homelessness and housing instability, for example, in developing each enrollee's care plan. We explained that a SNP could demonstrate this in several ways, consistent with its MOC, including making referrals to appropriate community partners and taking steps to maximize access to covered services that meet the individual's needs.

By standardizing certain data elements, our proposal would make those data elements available for collection by CMS from the SNPs for all enrollees. (States can also use their contracts with D–SNPs at § 422.107 to require reporting of these data elements in the HRAs to the State or its designee.) In the proposed rule at 87 FR 1859, we explained that, while we continue to consider whether, how, and when we would have the SNPs actually report data to CMS, we believe having such information could help us to better understand the prevalence and trends in certain social risk factors across SNPs and further consider ways to support SNPs in promoting better outcomes for their enrollees. We believe standardizing these data elements could also eventually facilitate better data exchange among SNPs (such as when an individual changes SNPs).

We understand that some States may separately require that Medicaid managed care plans collect similar information, potentially creating inefficiencies and added assessment burden on dually eligible individuals who are asked similar, but not identical,

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standardized patient assessment data under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP), Long-Term Care Hospital (LTCH) QRP, Skilled Nursing Facility (SNF) QRP, and the Home Health (HH) QRP due to the public health emergency. In the ''CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities'' final rule (86 FR 62240 through 62431), CMS finalized its proposals to require collection of standardized patient assessment data under the IRF QRP and LTCH QRP effective October 1, 2022, and January 1, 2023, for the HH QRP.

[27] CMS Innovation Center, ''The Accountable Health Communities Health-Related Social Needs Screening Tool.'' Retrieved from: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*.

[28] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2020. Retrieved from: *https://www.macpac.gov/wp-content/uploads/2020/06/June-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf*.

[29] For more information, see: *https://www.healthit.gov/isa/taxonomy/term/1801/uscdi-v2*.

[30] For more information, see: *https://prapare.org/the-prapare-screening-tool*.

[31] For the Accountable Health Communities Health-Related Social Needs Screening Tool, see *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*. The PAC assessment utilized the same transportation question as the AHC HRSN Tool.

questions in multiple HRAs. As we explained in the proposed rule, we believe that the benefit gained by all SNPs having standardized information about these social risk factors outweighs this potential risk. Where States are interested in requiring assessment questions, we recommended that States consider conforming to the standardized questions we implement for use under this final rule and, for integrated care programs, ensuring that plans do not need to ask the same enrollees similar or redundant questions. However, we also solicited input from States about what questions they are using and how we can best minimize assessment burden while ensuring that SNPs and States are capturing actionable information on social risk factors.

As discussed in the proposed rule at 87 FR 1860, we considered several alternatives to our proposal. We considered requiring fewer or more assessment questions on additional topics related to social risk factors or different combinations of questions, including questions on health literacy and social isolation. We considered soliciting comment on different examples of questions on housing, food, and transportation other than the examples included in the proposed rule. We considered simply proposing that all HRAs address certain domains (for example, housing), without authorizing CMS to specify the standardized questions to be used. We also considered specifying that the new questions only apply to certain enrollees and not others. We explained our rationale for not including these alternatives in the proposed rule at 87 FR 1860.

Finally, due to the processes associated with developing HRA tools, approval of MOCs, and MOC implementation, we discussed applying our proposed requirement beginning contract year 2024. However, we also considered whether to have our proposed requirement take effect at a later date, such as contract year 2025, to allow MA organizations more time to work our proposed new questions into their existing SNP HRAs. We solicited comments on our proposal and these potential alternatives. We also solicited comments on when CMS would need to issue sub-regulatory guidance providing the specific questions to be included in the HRAs to ensure that MA organizations would have sufficient time to incorporate the required questions.

We received the following comments on this proposal and respond to them below:

Comment: Most commenters expressed support for our proposal to require all SNPs to include questions on housing stability, food security, and access to transportation as part of their HRAs. Some commenters noted that inclusion of questions on these topics in HRAs would improve insight into enrollee needs. Several commenters stated that collection of information related to the SDOH can also better inform plans of enrollees' challenges and reduce barriers to optimal care and quality of life. A few commenters noted the importance of SDOH-related information in the development of an individualized, person-centered care plan. Some commenters expressed appreciation that CMS's proposal acknowledged the influence of the SDOH on health outcomes. Several commenters noted that social risk factors have a significant impact on health outcomes for the SNP population in particular. Several commenters noted that capturing social risk factors in SNP HRAs can help plans develop targeted interventions and connect enrollees to available supplemental benefits. A commenter believed health plans are best suited to collect this information and have the necessary resources to connect beneficiaries to social support services. Another commenter believed awareness of SDOH information improves care and lowers long-term costs. Other commenters noted that identifying unmet social needs among SNP enrollees could help reduce health disparities and advance health equity. A few commenters stated that that answers to HRA questions help capture information on social risk factors that is not only useful for individual enrollees, but also can be curated for evaluation at the population level in a way that can inform policy changes like payment reform. Another commenter believed HRA data on social risk factors have the potential to inform SNP supplemental benefit design and could be useful for incorporating social risk factors into future risk adjustment.

Response: We appreciate the widespread support for inclusion of questions on housing stability, food security, and access to transportation as part of SNP HRAs. We agree that requiring SNPs to collect information on these topics can allow SNPs to better understand enrollees' needs and challenges. As we noted in the proposed rule, our proposal would result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We also appreciate the commenters' support for reducing health disparities and advancing health equity more broadly. We agree that better identifying the needs of SNP enrollees can be an important first step toward these larger goals.

Comment: A number of commenters expressed support for the three question topic areas included in the proposed rule (housing stability, food security, and access to transportation). A commenter recommended CMS require all three categories be added to the HRAs. A few commenters noted these three topics are important indicators of social needs that are linked to individual health outcomes. A commenter noted that these three risk factors are issues that SNPs are well-positioned to address. Another commenter noted they supported the proposal and were already implementing an assessment tool that covered these three topics. Other commenters expressed support for all three topics, but noted transportation in particular. A commenter noted that problems with transportation can seriously impact access to care, and that advocates and beneficiaries report that these problems are widespread. Another commenter noted the importance of transportation for rural populations that may need to travel significant distances to providers. A commenter stated that SNPs armed with the knowledge that, for example, many of their members are experiencing access barriers due to a lack of transportation may wish to expand the availability of transportation benefits.

A commenter expressed support for all three proposed topics, but noted particular support for the inclusion of one or more questions about food security. The commenter believed that requiring screening for food insecurity will allow plans to better understand the important interplay between food insecurity and chronic illness in their enrollee populations, and will better equip plans to connect enrollees to critical responsive services such as medically tailored meals.

Response: We appreciate the support for our proposed HRA question topics. As we outlined in the proposed rule, we focused on housing stability, food security, and access to transportation because there is a large evidence base suggesting they have a particularly significant influence on the physical, psychosocial, and functional needs of the enrollees. These comments reinforce our belief that these three topics are the most important factors for which SNPs should be screening their enrollees.

Comment: Some commenters expressed support for the three topic

areas included in the proposed rule but recommended that CMS include questions on additional topics as well. Several commenters recommended adding a question about family and unpaid caregiver support. A commenter noted that understanding how much support a SNP member has at home—or the caregiving responsibilities they may have—has direct connections to health outcomes of SNP enrollees and may provide information on the prevalence of family caregivers and the need to better support them to help ensure members can continue to live in the community. Another commenter believed that addressing this topic and expanding supports for caregivers could reduce future reliance on Medicaid-funded LTSS and limit growth in LTSS expenditures. A few commenters suggested adding questions about caregiver burden in particular, noting that early recognition of caregiver burden can lead to targeted supports, and a lack of recognition of caregiver burden can prompt an emergency department visit or hospitalization. A commenter also suggested CMS add an assessment question about symptom burden, noting that the SNP assessment can be a powerful opportunity to identify poorly managed pain and symptoms and avoid crises like potentially preventable emergency department visits. The commenter recommended that, at minimum, questions about symptom burden as well as caregiver burden be required for SNP enrollees with certain serious illnesses, but also believed there are benefits to including those two topics in HRAs for all SNP enrollees.

Another commenter recommended multiple additional domains such as such as functional status, frailty, spoken language, and health literacy. Several other commenters encouraged CMS to include one or more questions on health literacy. A commenter noted that a question related to health literacy gets at the individual's ability to understand and ask questions about health information they receive, which the commenter suggested could have a significant impact on health outcomes.

Some commenters recommended CMS include questions on both health literacy and social isolation. A commenter noted that these two health-related social needs are prevalent among SNP populations and have direct impacts on health outcomes and behaviors, and expressed support for validated, concise screening tools on these topics, such as the Single Item Literacy Screener and AHC Model HRSN Screening Tool. Another commenter pointed to research showing that low health literacy is associated with nonadherence to treatment plans and puts patients at higher risk for hospitalization and mortality, and noted disparities in health literacy among different racial and ethnic groups. The commenter also believed the COVID–19 pandemic has highlighted weaknesses in the social support systems of older adults and at-risk populations, and noted that social isolation is associated with increased risk for premature mortality and significantly influences physical, mental, and cognitive health outcomes. A few commenters suggested CMS include a question on social isolation. A commenter recommended CMS include a question on social isolation rather than one on access to transportation. The commenter believed transportation has not been as high on the list of observed needs for SNP enrollees—they noted this was perhaps because many SNPs provide transportation as a supplemental benefit.

A few commenters recommended CMS include questions related to disability and functional limitations. These commenters believed that information related to the SDOH is not enough and that, without information on disability status, the assessment is incomplete and will perpetuate the disparities it seeks to uncover. Another commenter recommended including questions about interpersonal violence and its subdomains intimate partner violence and elder abuse, as well as utilities insecurity, and noted that the AHC HRSN screening tool includes these topics.

A commenter expressed support for CMS's three proposed topic areas, but noted some populations may not have those specific needs depending on individual circumstances or geographic location. The commenter believed an exclusive focus on these three social needs could miss other critical social needs that are more relevant, and noted that the relevance of different social needs questions will vary depending on individual circumstances, geographic location, populations served, and resource availability, among other factors. Another commenter noted that once the proposed HRA questions have been implemented successfully, CMS could consider adding new questions or expanding to other social needs topics, such as social isolation and access to telehealth.

Response: We appreciate the commenters' suggestions and acknowledge that the domains these commenters suggested are all important indicators of unmet enrollee needs. However, we maintain that the three topics we proposed have the strongest currently available evidence base [32] suggesting they have a particularly significant influence on health outcomes, and we still value parsimony in establishing new HRA requirements. Furthermore, the three topics on which SNP HRAs will be required to solicit information align with other efforts in this arena, such as the National Committee for Quality Assurance (NCQA) proposed Social Need Screening and Intervention HEDIS measure, which measures the percent of enrollees who were screened for unmet food, housing, and transportation needs, and received a corresponding intervention if they screened positive.[33] As we discuss in more detail later in this section, the requirement we are finalizing at § 422.101(f)(1)(i) allows SNPs flexibility to include questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation. The amendment we are finalizing to § 422.101(f)(1)(i) does not preclude SNPs from including additional questions in their HRAs as appropriate for their enrollee populations. The broad language at section 1859(f)(5)(A) of the Act and at § 422.101(f) provide SNPs a great deal of flexibility in developing their HRA tools to gather information about the unique physical, psychosocial, and functional needs of their enrollee populations in order to better meet those needs and coordinate care for the specific special needs population enrolled in the plan. Additionally, we may consider adding more, specific question topics in future rulemaking. We note that current regulations do not contain any specific requirements similar to what we are adopting in this rule, and we believe it is appropriate to first assess experiences implementing the change we are finalizing in this rule before proposing to require questions on other topics.

Comment: Some commenters recommended that CMS require collection of patient demographic information as part of the HRA, including a variety of factors, such as race, ethnicity, sex, gender, gender identity, sexual orientation, language, disability, and others. A few of these commenters noted collecting this information is important to understanding how demographic

[32] See, for example, Kushel M.B., Gupta R., Gee L., Haas J.S.. Housing instability and food insecurity as barriers to health care among low-income Americans. J Gen Intern Med. 2006;21(1):71–7. doi: 10.1111/j.1525–1497.2005.00278.x.

[33] *https://www.ncqa.org/blog/hedis-public-comment-period-is-now-open/.*

characteristics interact with each other intersectionally as well as with health outcomes, and is important to identifying disparities within a plan and in the SNP population more broadly. A commenter noted that collecting demographic information should be accompanied by quality improvement initiatives to reduce health disparities, such as improving a plan's ability to provide primary care in a culturally and linguistically appropriate manner. A commenter noted that demographic information can help facilitate a culturally sensitive care planning process for SNP enrollees. Another commenter expressed support for the proposal, but urged CMS to add safeguards to ensure the questions are framed and presented, and the answers are received, in respectful and culturally competent ways. The commenter encouraged all such questions to be posed only by people who have had training to combat implicit bias.

A commenter recommended ensuring that SDOH data standards are inclusive so there is not exclusion and further marginalization of populations due to limited definitions such as gender being defined as binary male or female, excluding individuals of other genders including nonbinary, agender, and transgender. Another commenter believed there is a need to move beyond individual SDOH factors to incorporate factors at the neighborhood, community, and zip code level, such as housing discrimination, to identify systematic and institutionalized forms of discrimination that may affect health.

A few commenters recommended that CMS include an option for an enrollee to choose not to respond to the proposed HRA questions to protect enrollee choice and privacy.

Response: We appreciate the commenters' input and agree that collecting enrollee demographic and other information can provide the plan with a more complete picture of the enrollee. We believe that many SNPs are already collecting demographic and other information as described in the comments, and therefore we have chosen to focus on the three topics we proposed for parsimony. The amendment we are finalizing at § 422.101 requires SNPs to include one or more questions on housing stability, food security, and access to transportation using questions from a list of screening instruments specified by CMS in sub-regulatory guidance. We believe this approach allows SNPs enough flexibility to choose questions that are the most appropriate for their enrollee populations while still maintaining some of the benefits of standardization. We encourage SNPs to ensure HRAs are conducted in a culturally sensitive manner. We also clarify that enrollees always have the option to refuse to answer an HRA question if they choose.

Comment: Some commenters suggested CMS require alternative or additional questions from those discussed in the proposed rule at 87 FR 1859 that cover the same three proposed topics or closely related topics. A commenter suggested CMS consider the National Comprehensive Cancer Network's Distress Thermometer assessment, a well-known screening tool among oncology providers, that includes housing, food security, and transportation among other topics. Another commenter noted examples of questions covering these three topics that are required for D–SNPs in the commenter's State. A commenter believed the examples in the proposed rule provided a good starting point for the subsequent sub-regulatory guidance, but also offered additional questions for consideration on topics related to those in the proposed rule, including questions about fall risk in the home, barriers to shopping for healthy food, and whether lack of access to transportation is persistent or infrequent, among other questions. Another commenter recommended CMS require SNPs to include in their HRAs questions across three specific housing specific domains, not just the proposed topic of housing stability: Homelessness, housing instability, and inadequate housing, noting that the AHC HRSN screening tool identifies all three housing topics. A commenter cautioned CMS against utilizing questions from the PAC assessment instruments. The commenter noted the patient assessment instruments used in each of the PAC settings are based on a ''medical'' model designed to determine medical care needs and associated resource use, and believed the information collected in the PAC assessments is insufficient to address ongoing social or medical needs.

Response: We appreciate the commenter's suggestions. As discussed in more detail later in this section, we are finalizing language at § 422.101(f)(1)(i) to require SNPs to include one or more questions from a list of screening instruments specified by CMS sub-regulatory guidance that complies with the Paperwork Reduction Act on housing stability, food security, and access to transportation (rather than requiring that all SNPs use the same specific standardized questions on these topics as proposed). We recognize that a variety of HRA questions on these topics could allow SNPs to collect meaningful information on their enrollees' needs. The requirement we are finalizing in this rule provides SNPs with some flexibility to select the specific questions on these topics that are most appropriate for their enrollees from the list of screening tools specified by CMS in sub-regulatory guidance. We remind SNPs that they may also choose to include additional questions that are related to the three required topics, but not exactly the same, such as fall risk in the home, for example.

Comment: A number of commenters expressed concern that the addition of the proposed questions to HRAs would make the assessments too long and burdensome. Several commenters suggested that CMS limit the number of questions SNPs must include in their assessments. A commenter recommended CMS limit the number of required questions to one question on each of the three proposed domains. A few commenters stated CMS should start with just a few questions and/or interoperable codes relating to housing, food, and transportation. Other commenters believed adding the proposed questions could reduce HRA completion rates.

Response: We appreciate the commenters' perspective on this issue. We believe that the potential benefit of SNPs having a more complete picture their enrollees' physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) outweighs the potential burden of including these questions in an assessment. Furthermore, because the requirement we are finalizing allows SNPs some flexibility to choose questions on housing stability, food security, and access to transportation from a list of screening tools specified by CMS in sub-regulatory guidance, SNPs can potentially continue using existing questions on these topics they already include in their HRAs if they are from the CMS-specified list, reducing the potential for administrative burden. We anticipate that the list of tools included in the CMS sub-regulatory guidance will likely include screening tools that are widely used in the industry and that SNPs may already be using for their HRAs. We will seek input on the list of screening instruments and comply with the Paperwork Reduction Act.

Comment: A commenter suggested that, instead of questions on the three proposed domains, CMS use a one-to-two-question pre-screener that asks enrollees their needs or challenges across a wider range of social needs (such as social isolation, employment, safety, legal needs, assistance with

utilities, issues with a person's living or home environment, material security, and digital access, in addition to housing, food and transportation). While the commenter recognized that social needs pre-screeners have not been widely used or vetted, the commenter believed pre-screeners could allow for a more holistic assessment of enrollee needs, which can then be followed up by additional questions if needed and be used to better inform care.

Response: We appreciate the commenter's suggestion; however, as the commenter noted, this approach has not been widely used or vetted. We prefer that SNPs use questions from validated or otherwise widely used assessment instruments (including any required by States), because we believe they will allow SNPs to collect high-quality, actionable information on their enrollees—at the individual level as well as at the population level—to more holistically understand the barriers to care enrollees face. While we are not familiar with exactly what type of questions would be included in such a pre-screener, we do not believe that a question that asks enrollees about their needs across such a wide range of domains is likely to receive useful responses. Because we believe using validated or otherwise widely used assessment instruments is important to understanding and addressing enrollee needs, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation.

Comment: A few commenters opposed requiring questions about social risk factors as part of SNP HRAs. A commenter recommended CMS give health plans the choice to include these questions on their HRAs to preserve assessment completion rates. Another commenter suggested CMS consider providing a list of standardized optional HRA questions, and noted that States could choose to require D–SNPs to include one or more optional questions in their HRAs, and individual plans could decide to include them as well. The commenter noted that plans using the optional questions could provide feedback to CMS on ease of use to help inform a future CMS decision about requiring these additional questions.

Response: We disagree with the recommendation to make questions about social risk factors optional for SNPs. We believe it is necessary to require SNPs to include questions about housing stability, food security, and access to transportation in order to have a more complete understanding of enrollees' physical, psychosocial, and functional needs. Though we are aware that many SNPs may already be asking their enrollees various questions related to SDOH, we want to ensure that, at minimum, SNPs are collecting information on these three key topics that are among the most influential to an enrollee's health outcomes. We remind commenters that SNPs currently have the option to include questions about social risk factors on their HRAs; making the proposed questions optional would not necessarily expand the screening of SNP enrollees for social risk factors from the level of screening that SNPs are doing currently.

Comment: A significant number of commenters expressed support for requiring standardized questions on the proposed topics. A commenter noted that standardized questions would streamline and facilitate ease in reporting, leading to improved data collection and higher quality data that more reliably measures impact and progress across populations. Another commenter believed that a lack of standardized data has impaired the ability of policymakers to fully understand the links between social risk factors and health inequities. Other commenters believed standardization would better ensure beneficiary needs are systematically identified and enable SNPs to develop and implement models of care to address those needs.

Several commenters noted standardized questions could improve SNPs' ability to understand prevalence and trends in social risk factors among enrollees. Several commenters also noted that standardized questions would enhance both SNPs' and CMS's ability to collect, analyze, and publicly report disparity- and equity-related data. Another commenter noted that developing standards for collecting and sharing SDOH-related data can result in actionable insights into disparities while improving data sharing across sectors. A commenter noted the importance of standardized data on food security in particular, stating that the use of standardized screening questions would provide data needed to better understand the impact of food insecurity and chronic illness across SNPs as a whole. A few commenters noted the importance of standardized assessment questions to data exchange between SNPs.

A commenter noted that there is a key need for standardized data on SDOH for interoperability purposes, the importance of which has been further amplified during the COVID–19 pandemic. A few commenters applauded CMS's intent to align the selected HRA questions with the SDOH data elements established as part of the USCDI v2. A commenter noted, however, there is still clarification needed to make certain the USCDI v2 questions would integrate seamlessly with traditional health information and result in successful interoperability.

A few commenters stated that implementing standardized questions such as those from the AHC Model screening tool would ensure that plans are using screening questions that have been tested for validity and reliability and to maximize opportunities to compare data across settings. Another commenter stated that SDOH-related information should be standardized across plans and Medicare programs to ensure the screening tools health plans are utilizing to capture this information are uniformly adopted across SNP, MA, Health Exchange and Medicaid plans.

A health plan commenter noted that they are already utilizing questions from the AHC HRSN screening tool to assess their enrollees and track their needs. The commenter noted that using this standardized tool has informed how they invested in internal capabilities and formed community partnerships to meet enrollee needs and improve their health. A few commenters stated that standardized questions would support plans' ability to address enrollee needs directly or to make referrals to social service organizations and programs. Another commenter believed that SNPs are in a unique position to meet enrollee needs because they have the flexibility to create unique benefit packages which can get to the root of many of the most important SDOH.

A commenter noted that they did not have a preference to which questions are specified (that is, from which standardized screening tool), but they strongly encouraged CMS to include standardized questions in sub-regulatory guidance and recommended that CMS coordinate with other HHS agencies to require the same set of standardized questions.

A commenter requested that CMS consider standardizing all questions on SNP HRAs to increase care coordination. Another commenter suggested CMS should provide clear definitions of housing, food, and transportation insecurity and word questions in a way to limit any ambiguity of the responses to increase the probability that MA plans get quantifiable, actionable data. They encourage CMS to reference existing tools and assessment questions when developing the standardized questions so that there is consistency with

screening tools already in use by providers and social services organizations.

Response: We appreciate the commenters' support for our proposal to require standardized questions, and the commenters' perspective that standardizing the collection of information on SNP enrollees' social risk factors would improve SNPs' ability to understand their enrollees' needs, track those needs over time, and improve interoperability and data exchange between plans as well as between plans and CMS, should CMS require the SNPs to report this data. We are finalizing an amendment at § 422.101(f)(1)(i) to require SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. However, we are not finalizing the part of our proposal that required SNPs to use specific standardized questions identified by CMS. We believe this middle-ground approach will retain some of the benefits of standardization while mitigating the potential downsides of using standardized questions, such as possibly (and unintentionally) limiting the opportunity to adopt questions that maximize cultural competence, potential increases in administrative burden and cost, and the potential for redundancy in States that have similar (but not fully aligned) requirements in their Medicaid programs. Requiring questions on the three topics from a CMS-specified list of screening tools, rather than specific standardized questions, will allow SNPs to choose questions from the specified tools on these topics that are most relevant to their enrollee populations.

We considered concerns about the administrative burden associated with modifying an HRA, as discussed in response to comments later in this section. We recognize that it could be burdensome for a SNP that is already asking questions on these topics in its current HRA to replace those questions with new ones from a CMS-specified list of screening tools. However, we believe that some degree of standardization helps ensure that SNPs are using validated questions and gathering high-quality, actionable responses from enrollees. Therefore, we are finalizing a requirement at § 422.101(f)(1)(i) for SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs.

In response to commenters who expressed support for standardization because of its potential for improved data collection and exchange, we recognize there is a need for greater interoperability in this area. Though we are not limiting SNPs to specific questions identified by CMS, we are requiring SNPs to use questions from a list of screening instruments specified by CMS in sub-regulatory guidance. While this provides a measure of flexibility for SNPs, by limiting the scope of available questions on these three domains to specified instruments, we expect there will be some degree of standardization. We anticipate including validated, health IT-enabled assessment tools on the CMS-specified list in order to maximize opportunities for standardized data collection and analysis. We also anticipate our sub-regulatory guidance will include screening instruments that have been developed with clear definitions of housing stability, food security, and access to transportation and that word questions in a way to limit any ambiguity of the responses and increase the probability that SNPs gather quantifiable, actionable data. As we develop the CMS-specified list in sub-regulatory guidance, we will consider existing requirements in other HHS programs, and will coordinate with agency partners to identify opportunities for burden reduction. In addition, the sub-regulatory guidance will include the option to use State-required Medicaid screening instruments that include questions on these domains.

In response to the commenter who requested that CMS consider standardizing all HRA questions, we note that we do not currently require any specific questions on SNP HRAs, and implementing such a large-scale requirement is outside the scope of this rulemaking.

We clarify that this requirement only applies to SNP HRAs, though other MA plans are free to include questions on these topics on the one-time HRAs they are required to make a best effort to complete within 90 days of enrollment under § 422.112(b)(4)(i).

Comment: Numerous commenters opposed the requirement to include standardized questions specified by CMS. A number of commenters recommended that CMS instead set more flexible guidelines that allow plans to select their own assessment questions, such as requiring questions on certain topics rather than dictating the questions themselves. Some commenters asked CMS to consider allowing SNPs that are already collecting information on the proposed topic areas in their HRAs to continue using their existing questions. Another commenter believed flexibility to select and customize assessment instruments and questions is the best approach to encourage screening for a broad array of needs and identifying an enrollee's most salient needs.

A commenter believed that requiring standardized questions would be expensive and cumbersome to change HRA questionnaires to match the CMS-specified question wording for plans that already actively work with SDOH assessment software vendors. Another commenter noted there is already a robust data collection environment in this area, and that payers and providers may have existing interoperable systems with their own definitions and language that encode social needs questions in HRAs and electronic health records (EHRs). The commenter believed the CMS proposal could require multiple organizations to modify data collection and IT systems and have significant spillover impacts into provider EHRs. Another commenter believed that prescriptive HRA elements would disrupt SNP operations and have an adverse impact on overall HRA completion rates. The commenter did not believe that the HRA questions themselves must be standardized in order for SNPs to have a more complete picture of their enrollees' risk factors.

A few commenters noted concerns about continuity in HRA data. A commenter expressed concern that, in the case of States and SNPs that have already been collecting this information, existing and baseline data could be lost or marginalized. Another commenter expressed concern that changes to their existing HRA would prevent them from doing effective historical data analysis.

Several commenters believed that requiring standardized questions would be burdensome for SNP enrollees, citing that enrollees may already be answering similar but slightly different questions in other assessments, such as in Medicaid programs. A commenter noted that most D–SNPs actively work with State partners to simplify data collection tools so that beneficiaries do not have to answer multiple questions with similar responses, and suggested that this proposal could get in the way of that coordination and lead to assessment burden among enrollees. A commenter expressed concern that beneficiaries would be required to answer multiple related questions solely as a result of this requirement.

Other commenters believed SNPs should be able to continue using their own assessment questions on topics

related to social risk factors because they tailored them to their specific enrollee populations and developed them over time to obtain more detailed information from enrollees. A commenter believed that standardized questions can lead to enrollees not feeling comfortable sharing information. Another commenter believed that CMS's proposal would prevent organizations from using validated questions they have determined work best to elicit information that is most effective in developing individualized plans of care for their enrollees. Another commenter believed plans are in the best position to review and revise their current HRAs to ensure collection of information and avoid overlap or unnecessary burden on enrollees.

A few commenters expressed concern about standardized assessment questions needing to be translated. A commenter stated that expectations of enrollees may differ in certain SNP service areas due to a range of cultural, linguistic, social, geographic, and economic factors, and believed that CMS should consider giving plans flexibility so that information on housing stability, food security, and access to transportation can be sought in a manner that is culturally and linguistically appropriate.

Response: We appreciate the commenters' concerns about requiring standardized questions in SNP HRAs. We recognize the challenge that CMS-specified standardized questions can pose to SNPs in terms of plan administrative burden and to enrollees in terms of potentially being asked multiple similar questions, and we acknowledge the commenters' perspective that SNPs are best-suited to develop questions that are most appropriate to their specific enrollee populations. We are also particularly sensitive to concerns about cultural and linguistic competence in HRAs. We agree with the commenter who stated that enrollee expectations may differ in different SNP service areas, and understand that an assessment question that is appropriate for one group of enrollees may be irrelevant or insensitive to another group. As discussed earlier in this section, we believe that the downsides of requiring specific standardized questions, including the potential administrative burden and duplication of existing efforts, outweigh the potential benefits of requiring specific standardized questions. However, we believe some degree of standardization helps ensure that SNPs are collecting high-quality, actionable responses from enrollees. We also believe using questions from a CMS-specified list of screening instruments increases the likelihood of SNP HRA data being shared in a meaningful way because the answers can be comparable across populations that are using the same questions. Therefore, we are finalizing language at § 422.101(f)(1)(i) that requires SNPs to include one or more questions from a list of screening tools specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. The sub-regulatory guidance will include the option to use State-required Medicaid screening instruments that include questions on these domains. We believe the requirement we are finalizing allows SNPs enough flexibility to choose questions that are appropriate for their enrollee population, given that they will be able to choose from a CMS-specified list of assessment tools. We also believe the requirement we are finalizing addresses commenters' concerns about the need to make burdensome changes to information technology (IT) and EHR systems to utilize CMS-specified standardized questions. We aim to include validated, widely available screening tools in our sub-regulatory guidance, similar to the tools included in the proposed NCQA Social Need Screening and Intervention HEDIS measure. We believe many plans may already be using questions from one or more of these types of screening tools. As a result, relative to our proposal, we believe there will be less need for systems, IT, and EHR changes.

Comment: Many commenters expressed concern that requiring standardized HRA questions would lead to duplication of efforts, given existing State and provider SDOH assessment requirements. A commenter noted that plans, providers, and States have been using a variety of different screening tools for years that focus on similar SDOH domains but with questions that may differ slightly. A few commenters stated they did not fully support the proposal because many providers are duplicating this work at the clinic level. A commenter cited work that has gone into building SDOH screening and navigation into provider offices. Another commenter noted that it is important to continue to have flexibility for providers to pursue more in-depth screening in the clinical setting as they deem appropriate.

A number of commenters noted concerns about how the SNP HRA requirement might overlap with existing efforts, particularly at the State level. A few commenters stated that dually eligible individuals may be asked similar, but not identical, questions in Medicaid managed care and in statewide D–SNP HRAs, and believed that the proposal to require standardized questions could therefore be challenging to implement. A commenter believed most D–SNPs already incorporate questions addressing social risk factors into their HRAs and actively work with State partners to simplify data collection tools and ensure the process is not burdensome for beneficiaries. A commenter recommended CMS give SNPs a menu of potential questions to include in their HRAs to potentially reduce overlap with other assessments. A few other commenters believed States should work with CMS on the development of standardized HRA questions and that CMS's rules should allow States to require alternative, standardized, State-specific HRA questions in addition to those CMS may specify in sub-regulatory guidance. The commenter believed this would improve alignment across each State's Medicaid program and reduce duplication for enrollees. Another commenter expressed support for standardization, but recommended that CMS allow for exemptions in cases where a State already requires assessments for social risk factors for Medicaid beneficiaries through other means, such as Health Homes and other Medicaid programs. The commenter noted that, in cases where community-based organizations are conducting care coordination activities such as assessments, standard measures and systems for collection can create a barrier due to the cost of systems, including updates or changes to existing systems, to support standardized data collection. A commenter believed that States would like to retain the right to modify D–SNP HRA questions to complement Medicaid assessment questions through the State Medicaid agency contract with D–SNPs required by § 422.107, and expressed uncertainty about whether that option would remain available under CMS's proposal.

Another commenter recommended CMS consider how to use information on social risk factors that is already being collected by different providers to populate a SNP enrollee's HRA when the information came directly from the enrollee within a given timeframe, rather than asking the enrollee to answer multiple similar questions.

A few commenters suggested CMS allow health plans to leverage community or provider organizations to complete these assessments. A commenter believed HRAs have a greater likelihood of being completed when conducted in the community

rather than by a health plan. Another commenter supported requiring standardized questions as outlined in the proposed rule, but encouraged flexibility in how the information would be gathered. The commenter noted they already require the same information as part of their State's comprehensive LTSS assessments.

Response: We thank the commenters for their input on how we can best minimize assessment burden while ensuring SNPs and States are capturing actionable information on these three social risk factors. SNPs can choose to utilize community-based organizations or other entities as subcontractors to conduct HRAs or portions of an HRA, and we have seen successful examples of this both with SNPs and MMPs. SNPs and MMPs are responsible for ensuring that their subcontractors meet all CMS care coordination requirements. As described in Medicare Part C Plan Technical Specifications for D–SNPs, CMS will accept a Medicaid HRA that is performed within 90 days before or after the effective date of Medicare enrollment as meeting the Part C obligation to perform an HRA, provided that the requirements in § 422.101(f)(1)(i) are met. We appreciate the commenters' concerns about duplication of efforts. We recognize that some SNPs, particularly D–SNPs, may already include questions related to housing stability, food security, and access to transportation on their HRAs to meet State requirements for assessing social risk factors. We also recognize that States may require D–SNPs to use particular assessment tools or questions on these topics to align with other State Medicaid initiatives or priorities, and that requiring SNPs to also include similar but not identical CMS-specified questions could result in redundant assessment questions that do not necessarily add to SNPs' knowledge of their enrollees' needs. When considered in combination with other concerns we discuss earlier in this section, we believe the potential downsides of requiring specific standardized questions—including potential redundancy and duplication of effort—outweigh the potential benefits of requiring all SNPs to use the same standardized questions. However, we maintain that some level of standardization is necessary to ensure SNPs are using validated questions and collecting reliable, actionable responses from enrollees. Therefore, we are finalizing language at § 422.101(f)(1)(i) that requires SNPs to include one or more questions on housing stability, food security, and access to transportation from a list of screening tools specified by CMS in sub-regulatory guidance in their HRAs but does not require SNPs to adopt standardized questions on these topics. We will consider State requirements in establishing the list of screening tools in sub-regulatory guidance. As a result, the sub-regulatory guidance will include the option to use any State-required Medicaid screening instruments that include questions on these domains. This modification to our proposal will allow SNPs to continue to use questions on social risk factors that States may already require and will prevent duplication of efforts.

Comment: Some commenters recommended CMS consider the use of standardized coding of responses rather than standardized responses. A commenter noted that with standardized data elements, assessment information would be interoperable to help plans, providers, States, and community-based organizations collectively identify and address social needs. Several commenters noted that standardized data elements would allow CMS to collect the assessment data and suggested that CMS specify a permissible set of SDOH screening tools to ensure the use of person-centered and validated tools without mandating specific standardized questions. A few of these commenters noted that requiring standardized data elements rather than standardized questions would be easier for SNPs to implement, potentially allowing them to continue to use their existing HRA questions that cover housing stability, food security, and access to transportation. A commenter noted this would allow SNPs to ensure HRA questions are culturally appropriate when translated across the many languages that SNP enrollees speak. The commenter also stated standardized coding would give plans the flexibility to ask questions in a way that accommodates the specific communication needs of enrollees, such as individuals with intellectual disabilities.

A commenter suggested CMS look to the Gravity Project for standardized value sets, interoperable codes, and HL7 technical standards to document standardized data on social needs. The commenter noted interoperable codes could include codes from ICD–10 Z codes, LOINC codes, and/or SNOMED code sets, among others.

Response: We appreciate the commenters' suggestions and will consider them as we develop the list of specified screening instruments in sub-regulatory guidance. We aim for SNPs to utilize questions from assessment tools that have the capability to facilitate data exchange as well as systematic analysis of prevalence and trends in their enrollees' social risk factors.

Comment: A commenter suggested that CMS create a standardized data submission tool to collect social risk factor-related data in a way most compatible to how the MA plans currently collect and report that data. The commenter expressed concern that requiring a standardized reporting format would cause MA organizations already actively collecting this data to undertake a potentially costly adjustment to their HRA operations. Another commenter stated health plans consistently identify the lack of standardization in SDOH data definitions and lack of harmony in scaling and scoring between assessment instruments as challenges. The commenter noted that requiring a specific instrument across settings and providers could solve this issue, but noted that another solution would be to allow for multiple screening instruments where items and scoring are cross-walked to create a universal scale. Several commenters recommended CMS allow SNPs to capture the required SDOH data using their own methods, including but not limited to HRAs, then crosswalk the data to CMS-specified data elements in order to report it to CMS. A few commenters specifically recommended that CMS work with experts to conduct a cross-walk of SDOH risk factor items from validated instruments and then create an acceptable equivalence to harmonize, calibrate and connect the items, scaling, scores, and findings from the various instruments to one standardized universal scale for each SDOH risk item. A commenter believed multiple data sources would be able to feed into the SDOH data that CMS could collect.

Response: We thank the commenters for these suggestions. We remind the commenters that CMS does not currently collect information related to social risk factors from SNPs. CMS currently only collects information regarding the number of initial and annual HRAs conducted as part of the Medicare Part C Reporting Requirements and reviews a sample of HRAs conducted by SNPs during audits. We will consider this feedback as we continue to consider whether, how, and when we would have SNPs report data to CMS.

Comment: A commenter believed that focusing on the annual HRA only as a source of information on enrollees' social risk factors would miss opportunities to better understand enrollee needs and would have limited

impact. A commenter noted that allowing SNPs to capture SDOH data outside of the HRA process would be sensitive to the personal nature of questions about social risk factors and allow the care team member the enrollee trusts the most to ask the questions. Another commenter believed CMS should allow collection of social risk factor information through HRAs or through other screening processes, and that CMS should require use of that social risk factor data in risk assessment and navigation to supports.

A commenter suggested that, instead of requiring plans to incorporate specific questions in their HRAs, CMS could require plans to include a minimum number of social needs-related questions in their HRAs, the SNP Model of Care, or as part of the Managed Care Manual Chapter 5 requirements. The commenter believed this alternative approach would fulfill the intent of the proposed requirement while providing plans the flexibility to leverage existing social risk factor questions they have already incorporated into their HRAs, minimizing the need for edits to existing HRAs.

Response: We appreciate SNPs' efforts to address their enrollees' unmet needs through their models of care, quality improvement projects, and various touchpoints with enrollees. We clarify that the new requirement at § 422.101(f)(1)(i) does not say that SNPs are to use the HRA as the only source of information on enrollee social risk factors. In addition to HRAs, we encourage SNPs to use sources of information outside of the HRA process in order to ensure that SNPs have a complete picture of an enrollee's physical, psychosocial, functional, and social needs and their personal goals. This can include, but is not limited to, interactions between enrollees and providers, care coordinators, other members of the integrated care team, or community-based organizations. This information can assist with the development of and any updates to an enrollee's individualized care plan. Though SNPs may use a variety of sources of information to better understand their enrollees' needs, we are finalizing a requirement for SNP HRAs to include questions from a list of CMS-specified screening tools about housing stability, food security, and access to transportation because all SNPs are required at § 422.101(f)(1)(i) to conduct a comprehensive HRA. Making this requirement part of the HRA ensures all SNPs are universally collecting this information, at minimum, in their assessments, regardless of any other sources of information on enrollee social risk factors they may use. As described elsewhere in this section, we have considered commenters' perspectives in coming to a final decision regarding a requirement to use CMS-specified standardized questions, and are instead finalizing language at § 422.101(f)(1)(i) that requires SNPs to include questions from a list of screening tools specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs.

Comment: Many commenters recommended CMS gather further input from stakeholders, including enrollees, plans, SDOH assessment tool developers, and providers, to develop the proposed standardized HRA questions before releasing sub-regulatory guidance. A few commenters suggested CMS convene a technical expert panel to consider research on the comparative effectiveness of existing social needs screening tools and to develop and test a social needs pre-screener. A commenter noted that the complexity of capturing social needs requires a thoughtful and multifaceted understanding of enrollee populations. Another commenter recommended CMS conduct a landscape review and align requirements to build off of what plans have already accomplished. A commenter suggested CMS initially gather information on one or two questions per SDOH topic so that plans can begin to incorporate standardized questions into their HRAs while continuing to use most of their own already-tested questions with enrollees. Another commenter believed CMS should not dictate specific questions without going through a consensus process for measure development, such as the National Quality Forum, and noted that SNPs should be able to incorporate CMS's required questions into their existing assessment tools.

A commenter urged CMS to seek provider feedback on the wording of standardized HRA questions. Several commenters suggested CMS incorporate direct enrollee input into any required HRA questions to ensure they are understandable and relevant to the intended audience. A commenter offered to provide CMS input into the development of the standardized questions that would work well across diverse enrollee populations. A commenter believed enrollees should have opportunities for feedback and oversight not only on screening questions, but also on any navigation and referral system a plan may use to meet the needs enrollees identify. Another commenter stated that CMS should not rush to use questions that collect questionable, unreliable, or inconsistent data.

Response: We thank the commenters for their suggestions. We agree that the complexity of capturing social needs requires a thoughtful and multifaceted understanding of enrollee populations. We are not finalizing the proposed requirement that SNPs use standardized questions specified by CMS on these topics. Instead, we are finalizing a requirement that SNPs use questions on these topics from a list of screening tools specified by CMS in sub-regulatory guidance. In developing this sub-regulatory guidance, we will consider the extensive work that health plans, the Federal Government, tool developers, and other stakeholders have already done to research and validate screening instruments. We clarify that we did not propose to create new measures, nor did we intend to require that SNPs adopt new assessment tools wholesale. Rather, we proposed to require SNPs to incorporate CMS-specified standardized questions about housing stability, food security, and access to transportation into their HRAs; we had intended that existing standardized questions, from existing validated assessment tools, would be specified by CMS for use by SNPs. Although we are not finalizing a requirement for SNPs to use CMS-specified standardized questions, we are finalizing a requirement that SNPs use questions from a list of screening instruments specified by CMS in sub-regulatory guidance. We anticipate this list will include validated, widely used assessment tools that include questions on housing stability, food security, and access to transportation.

Comment: Several commenters supported CMS's proposal to apply this HRA requirement across all SNPs. A commenter noted that all SNP enrollees are at elevated risk of experiencing health-related social needs. A few commenters recommended that CMS apply a requirement to screen beneficiaries for social risk factors beyond SNPs. A commenter suggested that CMS consider how to encourage all MA plans to screen beneficiaries for social risk. Another commenter encouraged an even greater expansion of this type of data collection across the Medicare program, noting that data collection by MA plans could provide a model for other providers in better understanding gaps in health equity especially given that racial minorities make up a larger percentage of MA enrollees than Original Medicare enrollees. Other commenters recommended that CMS work to implement social risk screening

consistently across both the Medicare and Medicaid programs.

Response: We appreciate the commenters' support and suggestions for expanding our proposed requirement beyond SNPs. We agree that greater prevalence of screening for social risk factors can help providers better understand health disparities for all MA enrollees and will consider future rulemaking on this subject. In this final rule, we are limiting the new requirement to include questions on housing stability, food security, and access to transportation on HRAs to SNPs because we believe SNP enrollees are more likely than other MA enrollees to have particular challenges with unmet social needs.

Comment: A commenter encouraged CMS to consider excluding institutional special needs plans (I–SNPs) from the requirement to include questions on housing stability, food security, and access to transportation in SNP HRAs. The commenter noted that all I–SNP enrollees reside in nursing facilities, which provide housing, meals, and transportation. The commenter also noted that nursing facilities are required to conduct minimum data set assessments and meet other requirements, and believed that requiring I–SNPs to assess enrollees for social risk factors would add administrative burden for the plan and potential confusion for enrollees with no apparent benefit. Another commenter believed that the proposal to include questions about housing stability in SNP HRAs was equally important to enrollees who reside in congregate housing as those who live in the community. The commenter noted that some residents of congregate housing may be spending down resources and believed it would be helpful to understand if an individual's current housing arrangements are precarious, potentially allowing a plan to connect them with needed services or resources.

Response: We disagree that assessing nursing facility residents for social risk factors in HRAs provides no apparent benefit. An enrollee residing in a nursing facility or other congregate housing setting can have concerns about the stability of their living situation. And, as we noted in the proposed rule preamble at 87 FR 1860, people may move between settings, including from an institutional placement to the community. In addition, I–SNPs may enroll individuals living in the community who require an institutional level of care, for whom housing stability could be of particular concern. I–SNPs, like other SNPs, are required at § 422.101(f)(1)(i) to conduct an initial as well as annual comprehensive HRA. We believe that the benefit of better understanding enrollee needs outweighs any potential burden of adding a few questions to the required assessment. However, we recognize that the types of questions that may be relevant for community-dwelling SNP enrollees may be less relevant for I–SNP enrollees who reside in a nursing facility. Therefore, we are allowing some flexibility for SNPs by finalizing regulatory language at § 422.101(f)(1)(i) which requires SNPs to include questions from a list of CMS-specified screening instruments on these three topics in the initial and annual HRA.

Comment: Numerous commenters provided feedback on the timing for enforcement of the proposal. A few commenters recommended requiring HRA questions on social risk factors as quickly as possibly rather than delaying until contract year 2025. A commenter noted that the three proposed question topics are already well-developed in 2022 and believed the questions are too important to delay beyond 2024. Other commenters expressed support for implementing the requirement in contract year 2024. Several commenters recommended CMS consider delaying implementation beyond 2024. A commenter requested that CMS make the effective date no earlier than 2025 to allow time for plans to design, test, evaluate, and operationalize the requirements. Another commenter recommended CMS provide sub-regulatory guidance on the specific standardized questions at least one year in advance of the required implementation to allow SNPs time for IT, system, and process changes. A few commenters suggested that CMS consider allowing flexibility in the time granted to implement standardized questions. Other commenters urged CMS to effectively communicate their requirements and implementation timeframe to States to allow time for States to remove any overlapping assessment requirements.

Some commenters stated they were supportive of a 2024 effective date only if CMS did not require standardized questions, and noted that, if CMS did require standardized questions, they requested an effective date no earlier than 2025 to allow SNPs sufficient time for implementation. A few of these commenters believed the implementation timeline should depend on the scope and complexity of the questions CMS ultimately requires.

A commenter encouraged CMS to give plans at least six months' notice of final requirements before the implementation date. A commenter noted that any change of assessment questions could have implications for EHR vendors that would need to implement such changes within an 18- to 24-month cycle. A plan commenter stated they would require 90 days to implement additional HRA questions.

Response: We appreciate the commenters' input on the implementation timeline for our proposal. We are finalizing a requirement at § 422.101(f)(1)(i) that SNPs must include questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food insecurity, and access to transportation beginning contract year 2024. We will ensure compliance with the Paperwork Reduction Act as we strive to post the sub-regulatory guidance by the end of 2022. This would leave more than a year from publication of this final rule for SNPs to come into compliance. The comments we received suggested that many SNPs already include questions on these topics in their HRAs. We believe many of the SNPs that are already including questions on these topics are using certain validated, widely available screening instruments. In our sub-regulatory guidance, we anticipate including validated tools that are already widely in use. Because we believe many SNPs are already using these types of screening tools, and because we are not requiring the use of specific standardized questions, we believe it is reasonable for SNPs to implement this requirement in contract year 2024.

Comment: Many commenters expressed concern about SNPs' responsibility to address social risk factors identified through the HRA. Several commenters noted that the HRA should be used to inform the enrollee's individualized care plan as well as to connect enrollees to covered services and community resources. A commenter noted that developing the enrollee's plan of care invites the SNP to form community partnerships that will allow them to address enrollee needs. The commenter believed these partnerships were crucial to reducing health disparities. Another commenter believed that assessments must be paired with strong connections to community-based organizations, including innovative approaches to payment for these organizations.

A number of commenters recommended CMS take steps to ensure SNPs are acting on the information they receive in HRAs. A commenter encouraged CMS oversight to ensure that HRA results are included in

enrollees' individualized plan of care. Another commenter believed CMS should emphasize that HRA questions related to social risk factors would help inform, but not direct, a provider's plan of care. A commenter expressed concern with CMS's statement, described at 87 FR 1859, that CMS would not be explicitly requiring that SNPs be accountable for resolving all risks identified in the HRA questions. The commenter believed CMS should require this type of accountability for SNPs. A few commenters requested CMS consider going beyond requiring HRA questions and work with plans to ensure that plans are not only assessing and referring enrollees to services, but also confirming that needed social services have been received. A commenter believed there needs to be a clear level of understanding of who is responsible for connecting a patient to services, and that there is potential for doing more harm than good by frequently asking enrollees about their social risk factors but not addressing them. A few commenters believed that screening without a strong referral and navigation system is ineffective, disrespectful, and unethical, and it can undermine enrollee trust in providers. Another commenter suggested that assessments for social risk factors be conducted on a monthly basis and even more frequently based on an enrollee's needs.

A few commenters urged CMS to consider how it can encourage and support plans to use data collected in HRAs in meaningful ways, and what guidance and resources it can provide plans on meeting enrollees' social needs. Another commenter urged CMS to establish oversight mechanisms and standards to ensure that SNPs have systems in place to assist enrollees based on the needs identified in the HRA. A commenter encouraged CMS to track HRA data to identify trends and potentially compare to the supplemental benefit offerings and utilization. Another commenter urged CMS to provide not just standardized questions but also guidance around framing, an explanation of why the questions are being asked, and expectation setting about how the information will be used to ensure it is maximally actionable.

Other commenters expressed concern about increasing demand for community-based services. A commenter noted that, even with services in place, enrollees may face access challenges, especially in rural areas. Another commenter believed that increasing screening for social risk factors would create more demand for an already-taxed community-based services infrastructure, which would inadvertently create new or exacerbate existing health disparities. The commenter recommended CMS work with the Administration for Community Living to continue to build community-based organizations' capacity to partner with health plans. The commenter also recommended CMS encourage financial investments in the community-based services infrastructure through value-based payments and flexible spending arrangements.

Response: We thank the commenters for their perspective on this issue. We agree that it is important for SNPs to not only assess their enrollees for social risk factors, but also connect them to needed services based on enrollee goals and preferences, whether such services are plan-covered benefits or referrals to community resources. We believe requiring all SNPs to include questions on enrollees' housing stability, food security, and access to transportation will help inform the comprehensive individualized plan of care required at § 422.101(f)(1)(ii); these individualized plans of care identify goals developed with the enrollee and measurable outcomes as well as describe specific services and benefits. At 87 FR 1859 in the proposed rule, we provided several examples of the ways in which SNPs could consult with enrollees about their unmet social needs as part of the development of individualized care plans, such as making a referral to an appropriate community partner. We appreciate the need for additional technical assistance on addressing the social needs of enrollees and will consider it in the future.

Comment: A commenter stated it is important to understand how the SDOH data that is collected through the new required questions is going to be used, including what the proposed output would be if those data elements are required to be reported to CMS.

Response: We clarify that the SDOH data collected as part of an HRA would be used to inform a SNP enrollee's individualized care plan based on the enrollee's goals. The language we are finalizing at § 422.101(f)(1)(i) does not require SNPs to submit HRA data to CMS. However, as we outlined in the proposed rule at 87 FR 1859, we continue to consider whether, how, and when we could have SNPs report this data to CMS under other regulations. If SNPs do submit this data to CMS in the future, we believe having such information could help us better understand the prevalence and trends in certain social risk factors across SNPs and consider ways to support SNPs in improving enrollee outcomes.

Comment: Several commenters suggested that CMS clarify that SNPs are not responsible for addressing all enrollee social risk factors identified during the HRA. A commenter requested clarification on whether CMS's expectation would be that these questions trigger care management outreach. Another commenter noted that plans often do not have the ability to address all the systemic barriers to achieving optimal health outcomes that may be identified in the HRA. A few commenters believed addressing social risk factors requires resources beyond what a SNP can offer, or may lie outside a SNP's control. A commenter believed that an organization's ability to address enrollee social needs depends on many factors, such as geographic location and resource availability in their communities, among others. Another commenter believed HRA questions about social risk factors could cause enrollee confusion, noting that an enrollee who indicates they are struggling to afford their rent may expect a health plan to provide a solution—perhaps a referral to a community housing resource—but then experience frustration and disappointment when a health plan is unable to do so.

A commenter expressed concerns about how SNP auditors may interpret this proposed requirement. The commenter believed that program auditors have demanded verification that such risks or needs are assessed and resolved. The commenter strongly encouraged CMS to include language in the SNP audit protocols emphasizing that the focus of this requirement, if finalized, is on assessment not resolution.

Response: We appreciate the commenters' perspectives on this issue. As stated at 87 CFR 1859, our proposal regarding the content of the HRA would not require SNPs to be accountable for resolving all risks identified in these assessment questions. The information gathered in the HRAs must be used to inform the development of the individualized care plan per § 422.101(f)(1)(i) and (ii). Section 422.101(f)(1)(i) requires the SNP to ensure that the results from the initial and annual HRAs are addressed in the individualized care plan. Section 422.101(f)(1)(ii) also provides that the individualized care plan must be developed and implemented in consultation with the beneficiary. The SNP must take steps to provide the services or connect the enrollee with appropriate services in order to accomplish the goals identified in the individualized care plan. The SNP can

take these social risk factors into account in the development and implementation of the individualized care plan, even if the SNP is not accountable for resolving all social risk factors. For instance, knowing that an enrollee is homeless or lacks reliable transportation could change how the SNP delivers covered services, such as by helping the enrollee find a primary care physician (PCP) that is more conveniently located or suggesting that the enrollee utilize a Federally Qualified Health Center (FQHC) in order to get multiple services delivered at the same time.

We remind the commenter who expressed concerns about how SNP auditors may interpret this proposed requirement that CMS welcomes stakeholder feedback on the audit protocols when the collection becomes available for public comment under the Paperwork Reduction Act of 1995. We also remind commenters of the requirement at § 422.503(b)(4)(vi) for MA organizations to adopt and implement an effective compliance program to prevent, detect, and correct non-compliance with CMS's program requirements, including the requirement at § 422.101(f)(1)(ii) that SNPs must develop and implement an individualized care plan.

Comment: Some commenters provided feedback on CMS's intent to provide the specific HRA questions through sub-regulatory guidance. Several commenters indicated they were supportive of this approach. A commenter agreed that it is important for CMS to retain the discretion to modify questions while still providing SNPs with clear requirements. Another commenter recommended CMS include a statement in sub-regulatory guidance to discourage States from adding their own questions and to encourage data sharing. A few commenters encouraged CMS to provide additional detail on how SNPs should implement this proposal.

Other commenters did not support CMS's intent to specify the questions in sub-regulatory guidance. A commenter believed this information should be standardized across plans and Medicare programs, rather than being specified in sub-regulatory guidance applicable to SNPs only. Another commenter strongly suggested CMS include any questions or specific requirements in regulation text because the commenter would like as much time as possible to implement changes, and believed the predictability of the regulatory cycle would allow them to better plan for policy changes.

Response: We appreciate the commenters' perspectives on use of sub-regulatory guidance to specify standardized questions. We believe that specifying the topics in regulation while providing additional operational detail in sub-regulatory guidance strikes the appropriate balance between the need for stability and predictability for plans and the need to be able to revise the specific questions to stay aligned with similar assessment tools. Although we are not requiring SNPs to use specific standardized questions, we believe a degree of standardization is necessary to ensure that SNPs are gathering high-quality, actionable responses from enrollees on their social risk factors. We also believe that allowing SNPs to choose questions from a list of screening instruments may increase opportunities for alignment with other efforts in this area, including NCQA's proposed Social Need Screening and Intervention HEDIS measure, as discussed in more detail later in this section. Therefore, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on each of these three topics. We believe the requirement we are finalizing addresses commenters' concerns about the lack of predictability involved in specifying required HRA questions in sub-regulatory guidance, since SNPs will be able to choose questions on these topics from the list of screening instruments in sub-regulatory guidance that best meet the need to assess housing stability, food insecurity, and access to transportation for the specific population they serve. We intend to issue the first sub-regulatory guidance on this issue by the end of 2022 and will revise and update the guidance as necessary in the future.

Comment: A few commenters recommended CMS consider privacy and confidentiality as part of this proposal. A commenter strongly urged CMS to provide adequate protection for and confidentiality of information collected through HRAs, noting that the collection and use of SDOH-related information should be held to the highest standard and that appropriate oversight and enforcement should restrict inappropriate use and access. Another commenter recommended CMS maintain high data security standards to ensure the collection of demographic information be conducted in a transparent, secure, and culturally sensitive manner for the targeted populations in question to reduce systemic bias. Another commenter asked for clarification as to whether the HRA is intended to be delivered by and stored as part of the EHR.

Response: We appreciate the commenters' concerns for protecting enrollee privacy. At a minimum, all MA plans, including the SNPs that are subject to this new requirement, must ensure the confidentiality of enrollee records under § 422.118 and the Health Insurance Portability and Accountability Act (HIPAA) Security and Privacy Rules at 45 CFR part 164. Enrollee records that must be protected under § 422.118 include the information collected as part of health risk assessments, and we believe that information gathered through SNP HRAs is protected health information (as defined in 45 CFR 160.103) subject to protection under HIPAA rules. We agree that information related to social risk factors is particularly sensitive and should be handled accordingly. We do not intend to specify how SNPs store this information. We remind the commenters that CMS does not currently collect this type of information from SNPs. Should CMS collect this information in the future, we will protect enrollee privacy as we do more broadly when handling beneficiary data.

Comment: Several commenters noted related efforts within and outside of CMS that they recommended CMS leverage when determining what questions to include in the HRA. A few commenters noted the Social Need Screening and Intervention quality measure under development from NCQA. Several others noted the work of the Gravity Project, supported by the Office of the National Coordinator for Health Information Technology, including the USCDI v2. A commenter strongly encouraged alignment with USCDI v2. A few commenters supported leveraging and aligning with the work of the Gravity Project, as well as ensuring alignment with other programs. A commenter noted CMS's proposal is consistent with the February 1, 2022 National Quality Forum Measure Applications Partnership recommendations to CMS for screening for social drivers of health and public data on those screening positive for social drivers of health. Another commenter cited a proposal for a similar quality measure for use in the Merit-Based Incentive Payment System for physicians and Inpatient Quality Reporting program for hospitals. A commenter also encouraged an approach that utilizes publicly available tools, such as the AHC HRSN screening tool, and does not require use of any specific proprietary screening tool.

Response: We appreciate the additional information and have been closely reviewing other SDOH efforts both within the Federal Government and other parts of the industry, including NCQA's proposed new Social Need Screening and Intervention HEDIS measure and discussion in the contract year (CY) 2023 Rate Announcement about comments received on potential future use of that proposed measure in Star Ratings. We recognize that there are a number of well-developed validated assessment tools with questions on the three proposed topics already in use by plans. We agree that our efforts should align with other programs. As we discussed in responses to earlier comments, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs must include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance about housing stability, food insecurity, and access to transportation in their HRAs, rather than requiring specified standardized questions. We believe allowing some flexibility for SNPs to choose questions best suited to their enrollee populations is important; however, we also believe some degree of standardization is necessary to ensure SNPs are collecting high-quality, actionable responses from enrollees. Furthermore, we believe this approach better allows us to align with other programs and SDOH efforts and retains the potential for improved data exchange and interoperability. For example, in response to the 2023 Advance Notice, the vast majority of commenters supported the use of NCQA's proposed screening and referral to services for social needs measure in MA Star Ratings. We believe our requirement would align well with potential use of that measure in Star Ratings. The proposed NCQA measure does not require use of a specific tool or questions, but would allow use of questions from a list of selected validated assessment instruments, similar to the new requirement finalized here at § 422.101(f)(1)(i). We anticipate our list of screening instruments in sub-regulatory guidance will overlap with the list of screening instruments NCQA includes in the specifications for its proposed measure, which will provide the opportunity for SNPs to align their compliance with the new requirement at § 422.101(f)(1)(i) with data to be used for the proposed NCQA measure. We believe the result will still be an increased ability for interoperable data exchange among SNPs.

Comment: A commenter requested clarification on several aspects of our proposal. The commenter questioned whether the HRA questions should be included on the initial, reassessment, and transition HRAs and whether each plan would be required to include the same questions on the HRA or whether it would be up to the individual plan to determine wording and how these new question sets fit into other existing domains.

Response: We appreciate the commenter's request for clarity. We clarify that the questions should be included in all HRAs used by SNPs. On the commenter's request for clarification about question standardization, we clarify that our original proposal would have required SNPs to use CMS-specified standardized questions. However, as discussed earlier in this section, we are instead requiring SNPs to use one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance in each of the three required domains. However, SNPs can determine how any new questions they add to their HRA in order to meet the new requirement fit into their existing assessment process.

Comment: A commenter requested CMS clarify how SDOH-related information may be used if an HRA identifies an issue that is not identified by a provider and asked how CMS intends to treat that information for other MA purposes.

Response: We thank the commenter for their questions and note that, per § 422.101(f)(1), the enrollee's providers should be included as part of the interdisciplinary care team (ICT) and the information from HRAs should be shared with the ICT as described in the SNP's MOC. As discussed in more detail in other comments and responses earlier in this section, the individualized plan of care for an enrollee must be developed in consultation with the enrollee and the care plan should address the results from HRAs. A provider is not required to independently identify a social health factor for it to be addressed in the care plan. As to the treatment of the information for other MA purposes, CMS does not currently intend to collect information about the responses on these newly required questions from SNPs. CMS may review HRAs and responses in order to determine compliance with the regulatory requirement.

Comment: A commenter encouraged CMS to allow for a wider range of providers who can conduct the HRA without the oversight of physicians and requested that CMS to continue to allow non-physician clinicians to conduct the HRA using telehealth under the supervision of a physician. They asked CMS to provide additional resources to community advocates, who can facilitate remote provider-patient interactions. A commenter suggested that enrollees, especially those with nutrition-related chronic conditions, should receive a referral to registered dietician nutritionists when food insecurity is identified.

Response: We thank the commenters and note that § 422.101(f)(1)(i) does not stipulate that specific plan personnel must conduct the HRA. CMS does not require physicians to oversee providers or other staff when conducting an HRA and allows SNPs flexibility to determine the level of clinical expertise needed to conduct the HRA. CMS does not preclude the use of telehealth to conduct HRAs. SNPs must conduct their HRA in a manner that is consistent with the plan's approved MOC; approval of the MOC is required by § 422.101(f)(3). We appreciate the information on community resources for referrals provided by commenters and will consider providing additional education on resources available to fill enrollee's needs as determined by the HRA and ways to support community-based organizations.

Comment: A commenter urges CMS to require that these standardized questions be made available and accessible in the preferred languages of the enrollees. They noted that for individuals with limited English proficiency, the inability to communicate adequately with providers serves as a barrier to accessing care.

Response: We appreciate the commenter's perspective on this issue. In § 422.112(a)(8), we require that MA organizations that offer MA coordinated care plans ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse ethnic and cultural backgrounds. The HRAs conducted by SNPs are key to developing individualized care plans for enrollees and such care plans are the foundation for furnishing, coordinating, and managing covered services to the special needs individuals who are enrolled in SNPs. Further, § 422.2267(a)(2) requires that, for markets with a significant non-English speaking population, MA organizations translate required materials into any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area. As HRAs are required by § 422.101(f)(1), SNPs are obligated to comply with

§§ 422.112(a)(8) and 422.2267(a)(2) in performing these assessments.

Comment: A commenter requested that CMS review and rewrite the technical specifications of the existing SNP care management reporting measure. They stated that, as currently written, a plan is required to conduct two HRAs (an initial and a reassessment) in the same calendar year for members who did not complete an HRA the previous year. They believe that the ''doubling up'' of HRAs in the same year can create member abrasion.

Response: This comment is out of scope of this final rule; however, we will consider it in future reporting specifications.

Comment: A few commenters stated that, under current statutory authority, SDOH cannot be used as primary targeting criteria for Special Supplemental Benefits for the Chronically Ill (SSBCI), just as secondary criteria when the three-part eligibility criteria have been met. The commenters recommend that CMS provide additional flexibilities to equip plans with the ability to address the social needs for which standardized data collection is being proposed in this rule. They recommend CMS consider allowing plans to use indicators of SDOH need outside of low-income subsidy status as primary targeting criteria through the Value-Based Insurance Design demonstration under Center for Medicare and Medicaid Innovation authority. They stated that this demonstration can serve as a pilot for potentially expanding the eligibility criteria for SSBCI in the future.

Response: We appreciate the recommendations for using SDOH data for determining eligibility for SSBCI and will consider it in the future. With regard to the commenters' recommendation that CMS provide additional flexibilities to equip plans with the ability to address social needs, we remind the commenter that, as discussed in more detail earlier in this section, SNPs must use the information gathered in the HRA to inform the development and implementation of the individualized care plan, and to ensure that the results of HRAs are addressed in the care plan per § 422.101(f)(1)(i) and (ii). We also remind the commenters that SNPs are not required to furnish housing, food, or transportation services. Changing the scope and criteria for SSBCI is outside the scope of this rulemaking.

Comment: A few commenters requested that CMS explore the potential use of standardized SDOH data more broadly in the Medicare Advantage program, such as in the Star Ratings program and in the CMS–HCC (hierarchical condition category) risk-adjustment model. Another commenter noted that the adoption and optimization of EHR infrastructure in low-resource settings is vital to increasing interoperability, as providers in underserved communities typically have outdated systems unable to integrate with other sources. A commenter also stated that the software development community is missing important guidance that would allow them to promulgate consensus-based standards for the exchange of SDOH data with providers and community-based organizations. A commenter strongly supported efforts to promote greater flexibility and alignment of provider payment incentives for care that address social needs and outcomes that advance health equity, noting that such measures can include incentives to increase provider uptake of evidence-based, high-value, low-cost services known to improve patient health outcomes.

Response: We agree that the use of SDOH data can provide us with a better understanding of enrollees. We thank commenters for raising these important issues. However, addressing SDOH and social risk factors in the context of payment policy, interoperability and EHR standards, and quality rating programs is outside the scope of this rulemaking. We note that CMS has discussed SDOH and social risk factors in other contexts, such as in the CY 2023 Rate Announcement, which discussed comments received on MA risk adjustment payment policy and use of a health equity index in MA/Part D Star Ratings. We appreciate the commenter's perspective on alignment of provider payment incentives for care to address social needs, but the topic is outside the scope of this rulemaking. Further, CMS is prohibited from requiring MA organizations to use particular payment arrangements with their contracted providers by section 1854(a)(6)(B) of the Act, but we will take these comments into consideration with regard to the Medicare FFS program and Innovation Center models.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing a requirement at § 422.101(f)(1)(i) for SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food insecurity, and access to transportation in their comprehensive risk assessment tool. However, we are not finalizing the proposal that SNPs use specific standardized questions.

5. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage. Those choices vary by market, and not all dually eligible individuals may qualify for all options, but they include Original Medicare with a standalone prescription drug plan, non-D–SNP MA plans, FIDE SNPs, HIDE SNPs, coordination-only D–SNPs, and Programs of All-Inclusive Care for the Elderly. Those choices can be complex and, for some, overwhelming.

Our own terminology is complex too. While we have defined terms through rulemaking in § 422.2, there remains nuance and variation that may make it difficult for members of the public—and even the professionals who support them—to readily understand what may be unique about a certain type of plan or what a beneficiary can expect from any FIDE SNP, for example. We proposed several changes to how we define FIDE SNPs and HIDE SNPs, citing our belief that they would ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries.

Comment: Numerous commenters expressed support of CMS's proposed changes to refine the definitions of FIDE SNPs and HIDE SNPs. MACPAC echoed this support and expressed the belief that CMS's proposal furthers integration and clarifies the definitions of FIDE SNPs and HIDE SNPs. MedPAC supported the proposed changes to the FIDE SNP requirements, stating that it believed the changes will help ensure that those plans are fully integrated with Medicaid and make it easier for beneficiaries to understand how they differ from other, less integrated D–SNPs. MedPAC also supported the proposed changes to the HIDE SNP requirements as an incremental step towards greater integration. Others also believed that CMS's proposal raises the standards for integration in SNP products. Several commenters agreed that the proposed refinements increase transparency of the options available for dually eligible beneficiaries. A commenter appreciated that CMS's proposal may encourage more States and health plans to provide integrated care for dually eligible individuals. Another commenter expressed support that the proposal would allow standards for quality measures set to be set more accurately, services provided more effectively, and plans held more accountable. A commenter stated that

Minnesota Medicaid products continued to meet the proposed definitions. A commenter urged CMS to require plans to make their status as a FIDE SNP or HIDE SNP more transparent to ensure beneficiaries and their advocates can understand the level of alignment and integration they should expect from their current or potential plan.

MACPAC cautioned that some States may need support to implement the new requirements and that there is some risk that the new requirements may lead to fewer FIDE SNP or HIDE SNPs available in the market. MACPAC suggested that CMS work closely with States and plans to remove barriers to offering FIDE SNPs and HIDE SNPs to make these integrated plans more available. Another commenter expressed a similar concern that States may choose to have less integrated systems due to limited State capacity and challenges with conflicting timelines for Medicaid requests for proposal and procurements and for CMS and D–SNP contracts. The commenter recommended several proposals to ease the burden for States, including CMS developing educational materials on the benefits of integrated care and CMS working with Congress to develop formal requirements and strategies to integrate care and increase State funding. Another commenter suggested that CMS encourage States to use a request for proposals process for FIDE SNPs to ensure FIDE SNPs are best positioned to support State and CMS goals for integration.

Response: We appreciate the robust support for our proposed changes to the FIDE and HIDE SNP definitions. We agree with commenters that the changes to the definitions will ultimately help differentiate the types of D–SNPs, clarify options available to beneficiaries, and improve and increase integrated coverage options for dually eligible individuals.

We appreciate the comments about States needing support to take actions that make HIDE SNP or FIDE SNP designation attainable for D–SNPs that operate in the State. CMS will continue to engage with States to promote integration, directly as well as by providing education to States about this final rule through our technical assistance contract with the Integrated Care Resource Center, which provides a range of written and live resources targeted to State Medicaid staff, such as sample contract language for State Medicaid agency contracts with D–SNPs, tip sheets describing exclusively aligned enrollment and other operational processes that support Medicare and Medicaid integration, educational materials and webinars about D–SNPs and highlighting State strategies for integrating Medicare and Medicaid, and one-on-one and small group technical assistance.

We acknowledge the suggestion for us to work with Congress on requirements and strategies to integrate care and increase State funding. While outside the scope of this rulemaking, we will consider whether there are additional opportunities to address this in the future. A Federal requirement for States to use a request for proposal process is outside the scope of this rulemaking, but nothing in this rulemaking prohibits States from using a request for proposal process to select the FIDE SNPs and affiliated organizations with which the State will contract.

Comment: A commenter recommended that in future rulemaking, CMS eliminate the distinction between HIDE SNPs and FIDE SNPs and that all D–SNPs in all States be required to meet a standard definition of full integration. The commenter also recommended limiting enrollment in full integration models, such as FIDE SNPs, to full benefit dual eligible individuals to improve integration in those models. Another commenter suggested that CMS should establish a glide path for phasing out HIDE SNPs to instead support FIDE SNPs. The commenter believes that lower tiers of integration are not sufficient to meet the needs of dually eligible individuals with disabilities.

Response: We appreciate the perspective shared by the commenters. We believe the distinction between HIDE SNPs and FIDE SNPs is meaningful and accounts for variation in State integration strategies, and therefore we are retaining HIDE SNPs. To clarify, in proposing that all FIDE SNPs have exclusively aligned enrollment, as discussed later in this section at II.A.5.a., all FIDE SNPs would be limited to full benefit dually eligible individuals beginning in 2025.

Comment: A few commenters expressed concern about State or Federal policies that may result in limiting the number or type of plan operating in a given market. A commenter requested that CMS continue to allow for HIDE SNPs and coordination-only D–SNPs to operate alongside FIDE SNPs required to have exclusively aligned enrollment as it promotes quality and value through competition and preserves freedom of choice. Another commenter recommended that CMS discourage any requirements that limit plan choice to a select few plans, particularly if these plans have limited or no experience servicing complex populations.

A few commenters expressed concern about the number of plan choices currently available to dually eligible beneficiaries. A commenter noted the number of plan choices and related information provided to beneficiaries results in a coverage landscape that is overwhelming to dually eligible individuals. The commenter further noted that more work is needed to increase awareness around integrated options and their potential value.

Response: We thank the commenters for sharing their perspectives. While our proposal makes changes to how we define FIDE SNPs and HIDE SNPs that we believe will ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries, we do not believe our proposal will directly limit the number or types of plans available for beneficiaries to choose from. We clarify that our proposal does not impact the ability for HIDE SNPs and coordination-only D–SNPs to operate alongside FIDE SNPs.

Comment: A commenter recommended that CMS revise the requirement that the MA organization offering the D–SNP and the Medicaid MCO contract holder must be the same legal entity in order to qualify as a FIDE SNP because, based on the experience of the commenter, there is no difference in a plan's ability to work with the State or integrate care for the members based on legal entity or parent organization status.

Another commenter expressed concern that the current definitions of HIDE and FIDE SNPs restrict plans that are operationally fully integrated from obtaining a FIDE SNP designation by requiring a Medicaid contract within the same legal entity that contracts with CMS to operate as a MA plan, while Medicaid contracts for HIDE SNPs only be provided by the same parent organization as that offering the MA plan. The commenter recommended that CMS amend the definition of FIDE SNPs to allow for the Medicaid contracts to be provided by the same parent organization that offers the MA plan because, in the commenter's view, this level of integration is sufficient to allow for full data sharing and coordination of benefits and is in keeping with the spirit of D–SNP regulations.

Response: We appreciate the comments but, because we did not propose to change that aspect of the definitions for FIDE SNPs and HIDE SNPs, we believe the suggestions are out of the scope this rulemaking. We believe that providing coverage of Medicare and Medicaid benefits through a single legal entity constitutes the most extensive

level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. However, we will consider these comments in future rulemaking.

Comment: A few commenters encouraged CMS to strengthen its oversight on State Medicaid rate setting to ensure that Medicaid rates for the MCO contracts held by FIDE SNPs are adequate and appropriately reflect the scope of the Medicaid services covered. A commenter noted that in some cases a capitated contract with a State Medicaid agency is held by a D–SNP's parent company or sister company, while in other cases the D–SNP entity itself may hold the contract. The commenter stated that, in the latter situation, Medicaid rules are not clear about the application of the Medicaid actuarial soundness requirements at 42 CFR 438.4 to the Medicaid benefits covered by those capitated contracts. Specifically, 42 CFR 438.4 applies to MCOs with comprehensive Medicaid contracts, prepaid inpatient health plans, and prepaid ambulatory health plans. The commenter noted that neither that rule nor the current CMS Medicaid Managed Care Rate Development Guide refer to D–SNPs or provide guidance on the applicability of Medicaid actuarial soundness standards to Medicaid services provided by D–SNPs. The commenter therefore requests that CMS formally clarify that capitation rates developed pursuant to State Medicaid agency contracts with D–SNPs are subject to the actuarial soundness requirements of 42 CFR 438.4.

Response: We appreciate the commenter's perspective on this issue. We clarify that the phrase ''capitated contract with the State Medicaid agency'' may be a Medicaid managed care contract for coverage of Medicaid benefits by a Medicaid MCO, or, for a HIDE SNP, a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP), depending on the scope of coverage of Medicaid services. All MCO, PIHP, and PAHP contracts are subject to the actuarial soundness requirements of 42 CFR 438.4. When the same legal entity as the MA organization that offers the D–SNP has the contract for coverage on a risk basis for Medicaid benefits—that is, when there is a capitated contract between the D–SNP and the State Medicaid agency—that contract may be an MCO, PIHP, or PAHP contract depending on the scope of benefits covered; in such cases, all of the applicable 42 CFR part 438 requirements for the MCO, PIHP, or PAHP contract, including the requirement for actuarially sound capitation rates, must be met. For example, Medicaid PIHPs and PAHPs can serve as the affiliated Medicaid managed care plan for delivery of Medicaid behavioral health or LTSS for HIDE SNPs.

a. Exclusively Aligned Enrollment for FIDE SNPs

Section 422.2 defines the term ''fully integrated dual eligible special needs plan''. Under the current definition, FIDE SNPs are plans that: (i) Provide dually eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid MCO contract under section 1903(m) of the Act with a State Medicaid agency, (ii) under the capitated Medicaid managed care contract (that is, the MCO contract), provide coverage, subject to some limited flexibility for carve-outs, of primary care, acute care, behavioral health, and LTSS, and coverage of nursing facility services for a period of at least 180 days during the plan year; (iii) coordinate delivery of covered Medicare and Medicaid benefits using aligned care management and specialty care network methods for high-risk beneficiaries; and (iv) employ policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

The current definition of a FIDE SNP does not require that the MA contract limit enrollment to the individuals who are enrolled in the affiliated MCO. An MA plan designated as a FIDE SNP may qualify for a frailty adjustment as part of CMS's risk adjustment of its MA capitation payments under section 1853(a)(1) of the Act and § 422.308(c). Section 422.2 also defines the term ''aligned enrollment'' as referring to when full-benefit dually eligible individuals who are enrolled in a D–SNP also receive coverage of Medicaid benefits from the D–SNP or from a Medicaid MCO that is: (1) The same organization as the MA organization offering the D SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, § 422.2 refers to that condition as exclusively aligned enrollment.

Exclusively aligned enrollment is an important design feature for maximizing integration of care for all the D–SNP's enrollees. As discussed on 87 FR 1861, it facilitates the use of integrated beneficiary communication materials and clarifies overall accountability for outcomes and coordination of care. FIDE SNPs and HIDE SNPs with exclusively aligned enrollment are applicable integrated plans subject to the requirement to use (beginning January 1, 2021) unified grievance and appeals procedures for both Medicare and Medicaid benefits.

As explained at 87 FR 1861, the current regulatory definition of FIDE SNP permits certain forms of unaligned enrollment between Medicare and Medicaid coverage. That is, a beneficiary may be in one parent organization's FIDE SNP for coverage of Medicare services but a separate company's Medicaid managed care plan (or in a Medicaid FFS program) for coverage of Medicaid services.

We proposed to amend the definition of ''fully integrated dual eligible special needs plan'' at § 422.2 with a new paragraph (5) to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment. Requiring all FIDE SNPs to have exclusively aligned enrollment would allow all enrollees to have their Medicare and Medicaid benefits under the FIDE SNP and affiliated Medicaid MCO explained clearly, which is made more difficult when some enrollees are, but others are not, also enrolled in the affiliated Medicaid MCO. Our proposed change would promote higher levels of Medicare-Medicaid integration by ensuring that that all FIDE SNPs can deploy integrated beneficiary communication materials and unify appeals and grievance procedures for all the Medicare and Medicaid benefits covered through the FIDE SNP and affiliated Medicaid MCO; such unified procedures are not feasible when some FIDE SNP enrollees do not receive their Medicaid benefits from the same organization.

Under our proposed definition, all FIDE SNPs would, by virtue of the same legal entity holding the MA and the Medicaid MCO contracts, (1) be capitated for Medicaid services, with some permissible exceptions proposed at §§ 422.107(g) and (h) and discussed later in this section, for all of their enrollees, and (2) based on meeting the definition of applicable integrated plans in § 422.561, operate unified appeals and grievance processes and continue delivery of benefits during an appeal.

As discussed in the proposed rule, absent a State Medicaid policy change in select States, our proposal would result in 12 current D–SNPs losing FIDE SNP status. However, our proposal would not prohibit those States and plans from operating as they currently

do but would simply mean that the affected plans would be HIDE SNPs rather than FIDE SNPs beginning January 1, 2025, and a consequence of this would be that the MA plans would not qualify for the frailty adjustment, as described in § 422.308(c)(4). States may also choose to require, through their State Medicaid agency contracts under § 422.107, that MA organizations create separate MA plan benefit packages (that is, separate D–SNPs), with one for exclusively aligned enrollment and the other for unaligned enrollment, the former of which would meet our proposed criteria and allow the organization to maintain FIDE SNP status for a share of its current FIDE SNP enrollment while using one or more new, separate D–SNPs for the unaligned enrollment. MA organizations would need to submit a request to CMS for a crosswalk exception under § 422.530(c)(4)(i), which we proposed in section II.A.6.a. of the proposed rule to redesignate from § 422.530(c)(4) without substantive change, for such enrollment transitions.

Finally, because the definition of aligned enrollment is specific to full-benefit dually eligible individuals, our proposal would also mean that D–SNPs enrolling new or continuing the enrollment of partial-benefit dually eligible individuals could not achieve FIDE SNP designation beginning in 2025. As discussed at 87 FR 1861 through 1862, we do not believe this would have any meaningful impact for plans currently operating as FIDE SNPs. Further we believe that the benefits to be achieved with FIDE SNPs having exclusively aligned enrollment for Medicare beneficiaries eligible for full Medicaid benefits, and the associated greater levels of integration in the provision and coverage of benefits and plan administration outweigh the potential negative effects of excluding partial-benefit dually eligible individuals. Partial-benefit dually eligible individuals would be limited to enrollment in HIDE SNPs, coordination-only D–SNPs, other MA plans, or the original Medicare FFS program.

Comment: Many commenters supported the proposal and noted that exclusively aligned enrollment advances full integration, strengthens care coordination between Medicare and Medicaid, improves enrollee communications, and better allows the FIDE SNP to unify processes that improve the beneficiary experience, such as through a single set of member materials and a unified appeals and grievances process. MACPAC commented that the proposal is consistent with its desire to move more States toward exclusively aligned enrollment. A few commenters expressed that FIDE SNPs should represent the highest level of integration and that this change would help clarify the currently confusing levels of integration among D–SNP categories.

In supporting the requirement for FIDE SNPs to have exclusively aligned enrollment, other commenters expressed that the current FIDE SNP structure is not designed to address the needs of enrollees who receive Medicaid services through fee-for-service or a misaligned Medicaid MCO. In these cases, commenters noted that a current FIDE SNP might be required to coordinate with different Medicaid MCOs or Medicaid fee-for-service and that lack of exclusively aligned enrollment is inconsistent with the otherwise-integrated FIDE SNP model. A commenter indicated including beneficiaries in FIDE SNPs who receive their Medicaid services elsewhere diverts plan resources, and another commenter indicated it does not afford a meaningfully integrated experience for enrollees, providers, or payers.

A few commenters indicated that exclusively aligned enrollment enabled plans and providers to develop and implement care models that are payer-agnostic, and a commenter indicated a FIDE SNP may enable a provider to submit a single claim for all services and cost-sharing.

Some commenters expressed appreciation for CMS's proposal to provide a crosswalk exception that would allow current FIDE SNPs that operate in States that do not require exclusively aligned enrollment to create separate PBPs for aligned and unaligned enrollees to maintain access to the frailty adjustment for aligned enrollees. Several commenters asked CMS to provide more detail on how this crosswalk would be initiated and approved.

A commenter agreed with CMS's analysis that making exclusively aligned enrollment a criterion for FIDE SNP status would cause minimal disruption to existing arrangements and leave ample fallback options for HIDE SNP status for the small number of plans that would be impacted by this change.

Response: We appreciate the widespread support for requiring exclusively aligned enrollment for FIDE SNPs. We agree that this proposed requirement would encourage a deeper level of integration of Medicare and Medicaid, improve beneficiary communications about covered Medicare and Medicaid benefits and services, and promote unified appeals and grievances. As we noted in the proposed rule at 87 FR 1861, we believe our proposal would clarify overall accountability for outcomes and coordination of care. We appreciate that it could also reduce provider administrative burden for contracting with FIDE SNPs. We agree that transitioning to HIDE SNP status is an option for existing FIDE SNPs in States where exclusively aligned enrollment is not in place by 2025 and that a small number of existing plans would be impacted by this change.

We clarify that the crosswalk exception being redesignated in this final rule to § 422.530(c)(4)(i) is available under current law. This crosswalk exception is available when a renewing D–SNP has another new or renewing D–SNP and the two D–SNPs are offered to different populations; the crosswalk exception permits within-contract movement of the enrollees who are no longer eligible for their current D–SNP into the other new or renewing D–SNP offered by the same MA organization if the enrollees meet the eligibility criteria for the new or renewing D–SNP and CMS determines the movement is in the best interest of the enrollees in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. This existing crosswalk exception may be available to implement a State's requirement to separate exclusively aligned enrollment from unaligned enrollment in separate PBPs. Our proposal was only to redesignate the regulatory provision to a different paragraph. When we issue the additional information on timelines and procedures for requesting crosswalks and crosswalk exceptions in sub-regulatory guidance, we intend to consider current timeframes and procedures for submission of applications, bids, and other required material to CMS, in addition to the need for MA organizations to make business decisions in a timely manner.

Comment: Several commenters opposed our proposal. A few commenters indicated that finalizing the proposal would limit the ability of States that exclude coverage of certain Medicaid benefits from their Medicaid MCO contracts (that is, States with Medicaid carve-outs) from pursuing more integrated models, may require modification of State-specific Medicaid processes for managed care enrollment, and could restrict enrollee choice in coverage. Another commenter discouraged any requirements that limit FIDE SNP offerings to Medicaid managed care organizations with contracts under section 1903(m) of the Act. Another commenter noted that a

State Medicaid agency decision not to facilitate exclusively aligned enrollment could lead to loss of FIDE designation and impact the frailty adjustment for an MA organization.

Another commenter expressed concern that the proposal limits plan choice where a beneficiary wanted to maintain access to a trusted provider or case manager in one Medicaid plan, while selecting an alternative Medicare plan based on supplemental benefits.

MACPAC recognized potential burden on States with FIDE SNPs that do not have exclusively aligned enrollment (Arizona, Pennsylvania, and Virginia) to make this adjustment and suggested CMS work with States to ensure there is a glidepath for these States. A commenter encouraged CMS to ensure that unaligned individuals and impacted providers in FIDE SNPs receive notices and counseling about the change and have access to continuity of care protections in Medicaid.

Response: We thank the commenters. We agree that requiring FIDE SNPs to have exclusively aligned enrollment would, in the absence of State policy changes, impact 12 existing FIDE SNPs in a few States (we identified Arizona, Pennsylvania, and Virginia in the proposed rule). States may also choose to require—through their State Medicaid agency contracts under § 422.107—that MA organizations create separate plan benefit packages, with one for exclusively aligned enrollment and the other for unaligned enrollment, which would allow the organization to maintain FIDE SNP status for a share of the existing FIDE SNP enrollment, as discussed at 87 FR 1861. As discussed in the proposed rule, these affected plans would be designated as HIDE SNP, rather than FIDE SNPs, beginning January 1, 2025, if the plans were unable to meet the new FIDE SNP requirements, and as such, we disagree that the proposal would limit States pursuing integrated care options, restrict member choice, or restrict the ability of States to facilitate access to D–SNPs. States and MA organizations may continue to use other structures for D–SNPs where enrollment is not exclusively aligned; those other plans, however, would not be FIDE SNPs.

Unaligned beneficiaries transitioned to a separate PBP would receive that information in the Annual Notice of Changes. We do not anticipate all beneficiaries will be disenrolled from existing FIDE SNPs that do not have exclusively aligned enrollment since an existing FIDE SNP could become a HIDE SNP or create separate PBPs, with one for exclusively aligned enrollment and the other for unaligned enrollment. In cases where an MA organization does transition unaligned beneficiaries to a separate PBP, we do not expect transitioning beneficiaries to encounter issues accessing providers since, in our experience, MA organizations tend to have the same provider networks across PBPs with overlapping service areas under the same contract. For these reasons, we disagree that we should require additional notification to enrollees in the affected plans.

The proposed rule did not ease the requirement in § 422.2 that FIDE SNPs provide coverage of comprehensive Medicaid benefits under a capitated contract between a Medicaid MCO and the State Medicaid agency under section 1903(m) of the Act. States may contract with HIDE SNPs and coordination-only D–SNPs if their Medicaid contracting strategies are not consistent with the new FIDE SNP requirements. We seek to move FIDE SNPs toward greater integration in the provision of Medicare and Medicaid benefits but this final rule does not eliminate less integrated approaches for other types of D–SNPs. We believe the benefits of exclusively aligned enrollment, including simplifying enrollee communication, allowing Medicare and Medicaid benefits to be explained more clearly, and unified appeal and grievance processes will differentiate FIDE SNPs from other plans. It will simplify the ways we, States, and benefit counselors communicate about FIDE SNPs by eliminating some of the confusing scenarios related to unaligned enrollment, as described in 87 FR 1861 of the proposed rule, and will allow FIDE SNPs to consistently and more clearly be the most integrated D–SNP option in the market. Exclusively aligned enrollment lays the groundwork for further integration of Medicare and Medicaid, giving States and plans the ability to improve the beneficiary experience such as through access to integrated beneficiary communication materials that describe available benefits, improve the enrollee experience, and decrease confusion by providing a simplified set of beneficiary materials.

Comment: A commenter recommended enrollee communications clearly articulate the features of integration and be communicated by a neutral party to support enrollee choice among coverage options. Another commenter asked CMS to assist States in understanding marketing materials.

Response: We appreciate the comments and we noted in the proposed rule that we believe the proposed changes to how we define FIDE SNP and HIDE SNP will help differentiate the types of D–SNPs and clarify options for beneficiaries. We will continue to work with States, plans, advocates, beneficiaries, and providers to improve model MA plan materials that describe D–SNPs and ensure that the features enabled by exclusively aligned enrollment are clearly communicated to beneficiaries. We will also continue to work with States to help them develop State materials and educate State Health Insurance Assistance Program (SHIP) counselors and Medicaid choice counselors to assist beneficiaries in understanding their coverage options. States may also want to leverage their beneficiary support systems as described in § 438.71.

Comment: A commenter noted the Massachusetts Senior Care Options D–SNPs and MMPs also limit enrollment in the Medicaid managed care plan to those members enrolled for Medicare, explaining that it substantially improves integration for all enrollees.

Response: We appreciate the commenter's perspective on this issue and we agree with the commenter that Massachusetts has achieved a high level of integration through Senior Care Options and One Care. We did not propose regulations limiting enrollment in the Medicaid managed care plan. As proposed and finalized, the amendments to the definition of FIDE SNP do not require that the State limit enrollment in the capitated Medicaid MCO to only those enrollees in the FIDE SNP for Medicare. Rather, this amendment limits the FIDE SNP designation to D–SNPs with State contracts requiring exclusively aligned enrollment. However, our proposal to require all FIDE SNPs to have exclusively aligned enrollment would not preclude a State from choosing to replicate Massachusetts' approach.

Comment: Another commenter encouraged CMS to continue to allow HIDE SNPs and coordination-only D–SNPs to operate alongside FIDE SNPs.

Response: We thank the commenter and clarify that the proposal would not restrict a State from allowing HIDE SNPs and coordination-only D–SNPs to operate in the same market as FIDE SNPs.

Comment: Several commenters supported the January 1, 2025, proposed effective date of this provision, while several other commenters suggested a delay to 2025 was not required, particularly for newly qualifying FIDE SNPs. Another commenter acknowledged the benefits of full alignment but noted implementation would require plan operational, policy, and system changes that would be

burdensome to implement by contract year 2025.

Response: We thank the commenters for their perspectives on the January 1, 2025 effective date. We believe there is sufficient time for FIDE SNPs to implement exclusively aligned enrollment for January 1, 2025. Through the Integrated Care Resource Center and CMS Medicare-Medicaid Coordination Office, we will provide technical assistance to States and plans interested in facilitating exclusively aligned enrollment and we are actively planning for upcoming technical assistance opportunities. We reiterate that MA organizations that are not interested in offering FIDE SNPs that meet the new requirements applicable beginning January 1, 2025 are not required by the changes finalized in this rule to do so because such MA organizations may offer coordination-only D–SNPs or HIDE SNPs that are subject to lower integration standards. The new requirement for exclusively aligned enrollment applies only to FIDE SNPs.

Comment: A commenter requested that the crosswalk option not be limited to States requiring or requesting exclusively aligned enrollment, but that the crosswalk option also include MA plan-initiated implementation of exclusively aligned FIDE SNPs and the creation of separate MA contracts.

Response: While we appreciate the request for MA organizations to initiate separate contracts in order to facilitate exclusively aligned enrollment, we clarify that under § 422.107(e) the separate contract would only be provided after CMS receives a request from a State. Section II.A.6.a. of this final rule discusses the proposal regarding § 422.107(e) and the corresponding crosswalk exception in more detail. The existing crosswalk exception at § 422.530(c)(4)(i) (redesignated in this final rule) is not limited to situations where a State has required or requested exclusively aligned enrollment but is limited to specific situations described in the regulation text where a renewing D–SNP has another new or renewing D–SNP under the same overall contract and the two D–SNPs are offered to different populations. In such instances, enrollees who are no longer eligible for their current D–SNP may be crosswalked into the other D–SNP.

Comment: A few commenters expressed support for the proposal to limit FIDE SNP enrollment to full-benefit dually eligible individuals and allow separate D–SNP PBPs for partial-benefit dual eligible individuals. A few commenters indicated that partial-benefit dually eligible individuals' characteristics are similar to full-benefit dually eligible individuals and that partial-benefit enrollees can benefit from access to stronger care coordination models not generally available in non-SNP MA organizations. The commenter believed this provision would allow the necessary distinctions in communications and enrollee materials describing access to Medicaid benefits for partial-benefit dually eligible enrollees compared to full-benefit dually eligible enrollees. A few commenters noted that separate PBPs based on whether enrollees are eligible for partial Medicaid benefits or full Medicaid benefits allows for targeting supplemental benefits to partial-benefit dually eligible individuals, and a commenter indicated it could potentially lead to some financial incentives for States to support D–SNP enrollment and possible shared savings opportunities.

Another commenter indicated any additional burden these changes may place on FIDE SNPs is preferable to disallowing enrollment of partial-benefit dually eligible individuals in D–SNPs as some policy makers have advocated and are far less restrictive than some other integration legislative proposals that have been promoted.

A few commenters expressed the proposal may create additional administrative burden for States, plans, and CMS for oversight and another commenter indicated that States may not have experience or processes to track PBPs, particularly when States may have a single MLTSS contract with a comprehensive benefit package with all enrollees included. The commenter indicated that having separate MA PBPs could create the need for additional Medicaid MCO contracts and additional rate-setting and contract review burdens both internally and with CMS. Another commenter asked CMS to provide technical assistance to States on procurement timing, contract support, full- and partial-benefit dually eligible individuals and applicability of unified appeals and grievances, and to encourage the use of crosswalks into PBPs for partial-benefit dually eligible individuals.

Response: We thank the commenters for the feedback. We noted at 87 FR 1861 through 1862 of the proposed rule that for contract year 2021, no FIDE SNPs enrolled partial-benefit dually eligible individuals. As such, we do not believe the preclusion of enrollment into FIDE SNPs by partial-benefit dually eligible individuals places additional burden on States, MA plans, or CMS for oversight or necessitates any new notifications to beneficiaries. We intend to provide education and outreach to States about changes codified in this final rule. To the extent that this new requirement for exclusively aligned enrollment for FIDE SNPs causes concerns for MA organizations or States that wish to have a single PBP for all dually eligible individuals, HIDE SNPs and coordination-only D–SNPs remain an option.

Comment: Several commenters recommended CMS provide training and technical assistance around exclusively aligned enrollment and its processes to States, plans, benefits counselors, and community partners. A few commenters asked CMS to provide more information and education to States and plans about operationalizing crosswalks to separate FIDE SNP PBPs with aligned enrollment with a companion Medicaid managed care plan from unaligned enrollment, as well as to separate PBPs for partial-benefit dually eligible individuals. A commenter recommended an intentional effort to ensure that dually eligible individuals, including those with limited English proficiency, understand how their enrollment works. The commenter recommended Community Catalyst's publication, ''Person-Centered Enrollment Strategies for Integrated Care Toolkit,'' for additional details on creating person-centered enrollment practices.

Response: We thank the commenters and agree that it is important for CMS to provide education and technical assistance to MA organizations in operationalizing provisions codified in this rule. In particular, we are working closely with California Department of Health Care Services to develop their exclusively aligned enrollment policies and procedures for 2023 and we will offer similar support to other interested States, regardless whether the use of exclusively aligned enrollment or FIDE SNPs is tied to transition out of a FAI demonstration or part of efforts to increase integration for dually eligible individuals.

Comment: Some commenters encouraged CMS to consider extending the requirement for exclusively aligned enrollment to HIDE SNPs, expressing that the rationale for exclusively aligned enrollment for FIDE SNPs is applicable to HIDE SNPs. MedPAC recommended requiring that HIDE SNPs have exclusively aligned enrollment, noting integration would depend on States and plan sponsors, who could either adopt exclusively aligned enrollment so the existing HIDE SNPs could continue to keep that designation or instead let those plans meet the lower coordination-only D–SNP standard for

integration. Further, MedPAC noted the use of exclusively aligned enrollment would also entail some disruption for full-benefit dually eligible beneficiaries who are enrolled in HIDE SNPs but have misaligned enrollment, as well as for any partial-benefit dually eligible individuals who are now enrolled in a HIDE SNP. MedPAC went on to state that requiring HIDE SNPs to use exclusively aligned enrollment could enable CMS to implement a range of policies that promote integration (such as requiring more D–SNPs to have Medicaid contracts to cover Medicare cost-sharing, integrated member materials, and a unified process for handling appeals and grievances) on a wider scale.

Also, a commenter stated opposition to extending exclusively aligned enrollment to HIDE SNPs.

Response: We appreciate the support for requiring exclusively aligned enrollment for both FIDE SNP and HIDE SNP. However, applying this requirement to HIDE SNPs is outside of the scope of this rulemaking. Further, additional factors, such as the potential burden and our goal of adopting requirements to more readily distinguish FIDE SNPs and HIDE SNPs, warrant continued consideration of this policy. We will consider these comments for future rulemaking.

Comment: A commenter requested CMS require matching Medicare and Medicaid effective dates for enrollment and disenrollment into FIDE and HIDE SNPs, leverage CMS mechanisms that can promote alignment, and provide technical assistance and encouragement to States to adjust their processes to ensure matching effective dates.

Response: We appreciate the commenter's perspective and agree that an important component of exclusively aligned enrollment is aligning the Medicare and Medicaid effective dates. There are operational challenges for aligning the timing of Medicaid and Medicare enrollment and disenrollment processes. States may have annual enrollment periods or continuous enrollment and many establish a mid-to-late month cutoff date for processing enrollments into Medicaid managed care plans. Medicare Advantage plans are required to utilize various election periods described at 42 CFR 422.62 and often must accept enrollments through the end of the month. We will work with States to support operationalizing exclusively aligned enrollment to maximize the ability to align enrollment and disenrollment dates. We plan to make available both written resources and technical assistance events promoting best practices that highlight States that successfully facilitate exclusively aligned enrollment, as well as offer direct State-specific technical assistance through the Integrated Care Resource Center. To maximize flexibility for States that newly implement exclusively aligned enrollment, we decline to codify in regulation the requirement that the effective dates are matching. However, we will monitor where there are misaligned effective dates upon implementation of this rule, and we will strive to provide technical assistance and share promising practices.

Comment: A commenter *recommended* that CMS, instead of finalizing the proposal, provide guidance and incentives to States to transition to exclusively aligned enrollment, such as adopting a shared savings component for FIDE SNPs, noting shared savings was used as an incentive to encourage States to participate in FAI. The commenter further recommended CMS consider a request for information to identify potential options and guardrails to address benefits, access, and quality.

Response: We appreciate the comment. CMS will continue to provide guidance and support to States that transition to exclusively aligned enrollment for FIDE SNPs, leveraging promising practices from States that already implement it, such as Idaho, Massachusetts, Minnesota, New Jersey, and New York. We decline to accept the commenter's recommendation to collect information in lieu of finalizing our proposal to amend the requirements for FIDE SNPs but instead will finalize as proposed. We intend to concurrently continue to collect promising practices and feedback and share it with States and plans. Finally, we note that payment requirements for MA plans are set by section 1853 of the Act so we have limited ability outside of the context of a demonstration or test of a payment model under section 1115A of the Act to change payment parameters in the MA program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment to the definition of FIDE SNP at § 422.2 with a new paragraph (5) to require FIDE SNPs, beginning January 1, 2025, to have exclusively aligned enrollment.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs and Solicitation of Comments for Applying to Other D–SNPs

We proposed to specify in § 422.2 that FIDE SNPs are required to cover Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to how section 1905(n) limits that definition to qualified Medicare beneficiaries (QMBs), as part of the FIDE SNP's coverage of primary and acute care; this means that the proposed amendment would require FIDE SNPs to cover Medicare cost-sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees. This proposal would cover Medicare cost-sharing in the form of coinsurance, copayments, or deductibles for Medicare Part A and Part B benefits covered by the FIDE SNP. Under this proposal, a FIDE SNP would cover Medicare payment for primary care and acute care covered by Medicare and the Medicaid payment for any Medicare cost-sharing in such cases.

We proposed this change only for FIDE SNPs because FIDE SNPs are the only type of D–SNP that must have capitated Medicaid contracts for coverage of Medicaid acute and primary care benefits and are better equipped, compared to other D–SNPs, to make improvements for coordination of benefits and adjudication of claims. This is especially true when capitation for Medicare cost-sharing is combined with a requirement for exclusively aligned enrollment (as discussed in section II.A.5.a. of this final rule to amend the FIDE SNP definition at § 422.2). Under our proposal, a provider serving a dually eligible individual enrolled in a FIDE SNP with exclusively aligned enrollment would submit a single claim to the FIDE SNP for both Medicare and Medicaid coverage of the service; the FIDE SNP would adjudicate the claim for a covered service for any applicable Medicare payment, Medicaid payment, and Medicaid payment of Medicare cost-sharing. As reflected in paragraph (1) of the definition of FIDE SNPs at § 422.2, the MA organization offering a FIDE SNP is also a Medicaid MCO with a contract under section 1903(m) of the Act, which must be a Medicaid managed care comprehensive risk contract as defined in § 438.2. In order to satisfy the new requirement, we proposed for FIDE SNPs, the Medicaid MCO contract will include capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits. (Like all MA plans, the FIDE SNP will cover Medicare Part A and Part B benefits, subject to limited exclusions for hospice, certain new benefits, and costs of acquisition of kidneys for transplant.) We expect the single legal entity to process and pay claims to the extent there is coverage under its MA contract and its Medicaid managed care

contract without the need for additional claims filing by providers. In this way, the additions we proposed to the definition of FIDE SNPs at § 422.2 would ensure that all FIDE SNPs include elements—capitation for Medicare cost-sharing and exclusively aligned enrollment—that result in improved beneficiary and provider experiences.

As discussed in the proposed rule (87 FR 1863), this policy does not include Medicare Parts A and B premiums in the requirement for FIDE SNPs to cover Medicare cost-sharing. The State Medicaid agency would continue to pay the Medicare Parts A and B premiums on behalf of dually eligible beneficiaries in accordance with §§ 406.26 and 406.32(g) and part 407, subpart C, of the chapter.

We received the following comments on this proposal and respond to them below:

Comment: All commenters supported the requirement of FIDE SNPs to cover Medicare cost-sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees as part of the FIDE SNP's coverage of Medicaid-covered primary and acute care services.

Response: We thank commenters for their support for our proposal.

Comment: A commenter supported the proposal but requested that CMS delay the applicability date of this provision to allow adequate time to implement in Tennessee where the capitated contracts do not currently include Medicare cost-sharing.

Response: In the proposed rule (87 FR 1863), we stated our belief that all FIDE SNPs already receive Medicaid capitation for Medicare cost-sharing consistent with our proposal. Therefore, we assumed no impact on current FIDE SNPs and did not believe there was any reason to delay the implementation of this new requirement. However, comments and our subsequent analysis illustrate that, in contrast to our assertion in the proposed rule, FIDE SNPs in one State (Tennessee) do not currently cover Medicare cost-sharing. As a result, we anticipate that there will be a need for the State and those FIDE SNPs to implement changes to come into compliance with this new requirement. Therefore, we are finalizing a change to make this provision applicable beginning in 2025.

Comment: A commenter encouraged CMS to ensure that capitation rates adequately and appropriately reflect the scope of services covered.

Response: We appreciate the opportunity to clarify that the requirements that apply to Medicaid capitation rates, including actuarial soundness requirements at 42 CFR 438.4, are applicable to Medicaid capitation rates developed for the affiliated Medicaid MCO for a FIDE SNP. As reflected in paragraph (1) of the definition of FIDE SNPs at § 422.2, the MA organization offering a FIDE SNP is also a Medicaid MCO with a contract under section 1903(m) of the Act, which must be a Medicaid managed care comprehensive risk contract as defined in § 438.2. As required by section 1903(m)(2)(A) of the Act and § 438.4, capitation rates for MCO contracts must be actuarially sound, meaning that the rates are projected to provide for all reasonable, appropriate, and attainable costs for the enrolled population that are required under the terms of the contract. CMS reviews such rates under Medicaid managed care regulations in 42 CFR part 438. We anticipate that capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits that will be required for FIDE SNPs will be included in the MCO contract that the single legal entity offering both the FIDE SNP and the MCO must have with the State. As such, the requirement for actuarially sound capitation rates will apply.

Comment: The commenter requested clarification whether this proposal is limited to covering Medicare cost-sharing for ''primary care and acute care'' and excluded providers and suppliers of other services (for example, pharmacists providing Part B drugs, DME suppliers, etc.) and, if the exclusion is intentional, why other providers and suppliers should be excluded.

Response: Thank you for the opportunity to clarify our proposal. The reference in paragraph (2)(i) of the FIDE SNP definition encompasses Medicare cost-sharing for all Medicare Part A and B services, including Part B drugs and DME to the extent the Medicaid program covers Medicare cost-sharing for full-benefit dually eligible individuals. We clarify here that in using the definition in section 1905(p)(3)(B) of the Act without regard to the limitation of that definition to QMB dually eligible beneficiaries, we are not requiring that a State expand the categories of full-benefit dually eligible beneficiaries for whom the State covers all Medicare cost-sharing in order to contract with a FIDE SNP.

Comment: A commenter asked if the Medicare cost-sharing for non-QMB dually eligible beneficiaries would be the financial obligation of the FIDE SNP and not included in the calculation of the State's capitated Medicare cost-sharing payment.

Response: Under this proposal, the FIDE SNP would cover Medicare cost-sharing, which includes coinsurance, copayments, or deductibles for Medicare Part A and Part B benefits covered by the FIDE SNP, for all enrollees of the FIDE SNP beginning January 1, 2025. As detailed in section B.5.a of this rule, FIDE SNPs must have exclusively aligned enrollment beginning January 1, 2025, FIDE SNPs will only enroll full-benefit dually eligible individuals, which can include non-QMB full-benefit dually eligible beneficiaries, and cover Medicare cost-sharing for these enrollees beginning January 1, 2025.

For full-benefit QMB dually eligible individuals (that is, QMB+ beneficiaries), ''Medicare cost-sharing'' includes costs incurred with respect to dually eligible individuals in the QMB program ''without regard to whether the costs incurred were for items and services for which medical assistance [Medicaid] is otherwise available under the plan'' as described in section 1905(p)(3) of the Act. Therefore, under the new requirement we are finalizing here, the FIDE SNP capitated contract with the State must include State payment of Medicare cost-sharing for full-benefit QMB dually eligible beneficiaries. States may elect to extend coverage of Medicare cost-sharing, including coinsurance, for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs, (such as SLMB+ beneficiaries), as specified in the Medicaid State plan. For non-QMB full-benefit dually eligible beneficiaries, the FIDE SNP capitated contract with the State must include State payment of all Medicare cost-sharing when the State has elected to extend such coverage for these individuals. Absent such an election, the FIDE SNP's affiliated Medicaid MCO capitated contract must cover Medicare cost-sharing for these non-QMB full benefit dually eligible individuals only for services covered under the State plan. In this last circumstance, the State might adjust the capitation rate paid under the Medicaid MCO contract to reflect coverage of Medicare cost-sharing for non-QMB full-benefit dually eligible individuals only for those services, such as inpatient hospitalization, that are also covered under the Medicaid State plan. In our experience, however, States do not adjust the capitation rate for Medicare cost-sharing for a FIDE SNP's full-benefit dually eligible enrollees to account for those few Medicare-covered services not covered under the Medicaid State plan because the difference in per

member per month costs is not significant.

Comment: A commenter asked how the State coverage of cost-sharing occurs in situations where a FIDE SNP makes alternate payment arrangements with providers (for example, if a FIDE SNP capitates per patient per month payments, quality bonuses, or within a network with salaried providers and facilities directly owned by the plan).

Response: When the State contract with the Medicaid MCO affiliated with a FIDE SNP capitates for Medicaid payment of Medicare cost-sharing, providers no longer bill the State Medicaid agency for Medicare cost-sharing; the FIDE SNP assumes responsibility for making these payments. As proposed and finalized, the requirement for FIDE SNPs to cover the Medicaid payment of Medicare cost-sharing for their enrollees under the capitated contract between the Medicaid MCO affiliated with the FIDE SNP and the State does not dictate the particular payment amounts for covered services. Nor does this final policy address all operational details for identifying Medicare cost-sharing obligations for specific services in the context of specific provider payment arrangements. This new provision only requires that the FIDE SNP's coverage of Medicaid benefits include the Medicare cost-sharing otherwise applicable for Medicare Part A and B benefits for the FIDE SNP's enrollees, which will result in the FIDE SNP's payment to a provider including the FIDE SNP's coverage of the service and any Medicaid-covered Medicare cost-sharing amount.

CMS does not interfere in the negotiations between MA organizations and their contracted providers and does not directly participate in the negotiations between FIDE SNPs and States regarding the capitation amount paid for FIDE SNP's Medicaid coverage (other than to assure that Medicaid managed care requirements for actuarially sound rates in §§ 438.4 through 438.7 are met). CMS will not be in a position, nor have the responsibility, to assess payment methodologies for how the FIDE SNP pays the covered Medicare cost-sharing amounts to their contracted providers or whether those payments are equivalent to comparable payments through Medicare and Medicaid FFS. States can require use of particular payment methodologies for certain providers, such as primary care, mental health, and other high value providers, through contracts with D–SNPs to ensure sufficient access and quality of care meets the needs of D–SNP members. In addition, Medicaid managed care regulations permit States to direct Medicaid managed care plans to use certain payment arrangements in connection with Medicaid coverage provided certain requirements are met at § 438.6(c). Finally, as previously noted in this rule, we review Medicaid capitation rates to ensure they are actuarially sound.

Comment: A commenter requested CMS consider clarifying elements of the Medicare cost-sharing billing process during a beneficiary's Medicare deeming period to prohibit MA providers from billing Medicare cost-sharing to dually eligible beneficiaries during the Medicare deeming period in order to strengthen balance billing protections for dually eligible beneficiaries.

Response: We share the commenter's concern about the billing of Medicare cost-sharing during the deeming period when a D–SNP enrollee has lost Medicaid eligibility. However, the loss of Medicaid eligibility also means that the prohibition on providers billing the beneficiary for Medicare cost-sharing has also been lost, since the individual is no longer dually eligible for Medicare and Medicaid. We will take this comment into consideration as we work to develop ways to protect individuals from undue expenses and potential access to care barriers during the deeming period. Although these individuals have lost eligibility for Medicaid, they almost always still have very low income, very few resources, and substantial health care needs.

Comment: A commenter requested clarification on how best to apply this requirement in instances where the HIDE SNP or FIDE SNP includes language on capitation for Medicare cost-sharing in the plan's contract with the State, but the State is not paying the plan for the Medicare cost-sharing in accordance with the contract language.

Response: As proposed and finalized, capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits that will be required for FIDE SNPs will be included in the Medicaid MCO contract that the single legal entity offering both the FIDE SNP and the Medicaid MCO must have with the State. Future contract disputes regarding the implementation of State capitated payment for Medicare cost-sharing to a FIDE SNP should be addressed per the Medicaid MCO contract language for dispute resolution. The requirement for capitated coverage of Medicare cost-sharing does not extend to HIDE SNPs; however, States and HIDE SNPs (and other MA plans) are free to negotiate capitated arrangements for facilitating Medicaid coverage of Medicare cost-sharing for dually eligible individuals.

We appreciate the support for our efforts. We are finalizing our proposed revisions for paragraph (2)(i) of the definition of a FIDE SNP at § 422.2 with a delay in the applicability date until the 2025 plan year for the requirement that FIDE SNPs cover Medicare cost-sharing in their capitated contracts with State Medicaid agencies.

In the proposed rule (87 FR 1862 through 1863) we also solicited feedback on the feasibility, implementation, estimated time to enact, and impact of requiring all D–SNPs to have contracts with State Medicaid agencies for capitated coverage of Medicare cost-sharing to inform future rulemaking. We received many comments in response to our request for information. All comments supported the benefits to requiring capitated Medicare cost-sharing for all D–SNPs, however commenters expressed substantial concerns regarding the implementation of such a policy and how to determine if such a policy achieves the purpose of improving provider access for dually eligible individuals. Commenters provided suggestions regarding implementation timeline, development of resources, and technical assistance.

As we discussed in the proposed rule, we also considered proposing a requirement for State Medicaid data exchanges to provide real-time Medicaid managed care plan enrollment data to D–SNPs to enable better coordination between the D–SNP and the State and/or Medicaid managed care plan. To allow more time for us to consider the operational challenges for States, we did not propose a requirement. We solicited feedback on the pros and cons of requiring State Medicaid data exchanges to provide real-time Medicaid FFS program and Medicaid managed care plan enrollment data with D–SNPs, and the impact of such a requirement on States, Medicaid managed care plans, D–SNPs, providers, and beneficiaries. We received a number of comments in response to our request for information on the pros and cons of requiring State Medicaid data exchanges of Medicaid FFS program and Medicaid managed care plan enrollment data with D–SNPs. All commenters agreed with CMS's assessment of the importance of this data to enable better coordination between D–SNPs and the Medicaid FFS program or Medicaid managed care plan for dually eligible beneficiaries that are not in aligned plans. Many commenters suggested a technical expert panel of States and plans to develop the concept and identify considerations, obstacles,

and implementation timeline for the described data exchange. Finally, we received a couple comments that were concerned with the uniformity of individual State Medicaid data exchanges, and a commenter suggested leveraging the State MMA File Exchange [34] as a better alternative for sharing the Medicaid FFS program and Medicaid managed care plan enrollment data.

We appreciate the support for our efforts to raise this issue and will consider comments and suggestions received for future rulemaking, technical assistance, and related work.

c. Scope of Services Covered by FIDE SNPs

(1) Need for Clarification of Medicaid Services Covered by FIDE SNPs

CMS first defined the term ''fully integrated dual eligible special needs plan'', or FIDE SNP, at § 422.2 in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' final rule (76 FR 21432) (hereinafter referred to as the April 2011 final rule) to implement section 3205(b) of the Affordable Care Act (which amended section 1853(a)(1)(B)(vi) of the Act to add a frailty adjustment to the risk adjustment payments for certain FIDE SNPs). That definition provided that a FIDE SNP must have a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, consistent with State policy.

As discussed in more detail in the proposed rule (87 FR 1864), despite discussion in the April 2011 final rule that FIDE SNPs would provide all primary, acute, and long-term care services and benefits covered by the State Medicaid program, we did not operationalize review of State Medicaid agency contracts in that way. Over the years, CMS has determined D–SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, and LTSS benefits from the Medicaid coverage required from the D–SNP. In effect, we allowed States flexibility in the coverage provided by FIDE SNPs, not only to accommodate differences in the benefits covered under various State Medicaid programs but to accommodate differences in State contracting strategies for managed care broadly, and for FIDE SNPs in particular. In the April 2019 final rule (84 FR 15706 through 15707), we revised the FIDE SNP definition at § 422.2 to add Medicaid behavioral health services to the list of services that a FIDE SNP must include in its capitated contract with the State Medicaid agency. But, consistent with how we were operationalizing this definition, we explained that our amendment would allow plans to meet the FIDE SNP definition even where the State excluded Medicaid behavioral health services from the capitated contract.

As discussed in the January 2022 proposed rule (87 FR 1863 through 1864), the way we have applied the definition of FIDE SNPs has not enabled us to ensure FIDE SNPs fully integrate Medicare and Medicaid services for dually eligible individuals. We proposed to revise paragraph (2) of the definition of a FIDE SNP at § 422.2 to clearly specify which services and benefits must be covered under the FIDE SNP capitated contract with the State Medicaid agency, and thus bring fuller integration of Medicaid benefits to individuals enrolled in FIDE SNPs. Our proposal would revise paragraph (2) of the existing definition into paragraphs (2)(i) through (v), with each of the new paragraphs addressing specific coverage requirements. We believe the proposals described in this section strike the appropriate balance between flexibility for variations in State Medicaid policy and our goal of achieving full integration in FIDE SNPs. In addition, as discussed more fully in section II.A.5.e., our proposed revision of the definition, in conjunction with a proposal to add § 422.107(g) and (h), included flexibility for approval of some limited carve-outs of LTSS and behavioral health services.

As described in the proposed rule (87 FR 1864), we proposed that the updates to the FIDE SNP definition at § 422.2 would mean that all Medicaid benefits in these categories would be covered by the MCO that is affiliated with the FIDE SNP, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in the FIDE SNP, and we did not propose any exceptions. Because the same legal entity must have the MA contract with CMS for the D–SNP and the Medicaid MCO contract with the State, and the enrollment in the FIDE SNP must be limited to dually eligible individuals who are also enrolled in the MCO, this entity is functionally all the FIDE SNP.

Comment: Several commenters supported CMS's proposed clarification of the services that must be covered by a FIDE SNP through a capitated contract with the State Medicaid agency. Other commenters supported CMS's proposed changes to the FIDE SNP requirements and believed that they would help ensure that FIDE SNPs are fully integrated with Medicaid. Several commenters expressed that the proposed changes would make it easier for beneficiaries to understand how FIDE SNPs differ from other, less integrated D–SNPs. A commenter stated that all full benefit dually eligible individuals should have access to fully integrated care, which should include one benefit package that encompasses all Medicare- and Medicaid-covered services, including primary and acute care benefits, behavioral health, LTSS and dental benefits. A commenter supported CMS's proposal because they experienced firsthand in the Financial Alignment Initiative how Medicare-Medicaid integration greatly benefits enrollees, providers, and payers. Another commenter believed that providers would experience lower administrative burden when contracting with FIDE SNPs that provide comprehensive coverage of all the services described in our proposal. A commenter supported CMS's proposal because it accounts for variations in State Medicaid programs, honors beneficiary choice, and promotes quality and value through competition.

Response: We appreciate the widespread support for our proposal to clarify the scope of Medicaid-covered services that must be covered by the affiliated Medicaid MCO for a D–SNP to be a FIDE SNP. We agree that the proposed changes will help ensure fuller integration of benefits for FIDE SNP enrollees. We also agree that the proposal will improve stakeholder understanding of how integrated plan options differ and improve clarity of what those plans cover.

Comment: A commenter believed that the proposed changes to the definition of a FIDE SNP would negatively impact Medicaid programs in a number of States because some plans currently designated as FIDE SNPs would no longer be considered FIDE SNPs. Another commenter opposed CMS's proposal because they believed that the proposal would discourage States wishing to pursue further integration from doing so as it may not align with the State's other Medicaid contracting priorities. The commenter noted that Pennsylvania, Virginia, and Arizona have made the decision to permit D–

[34] Since 2005, State Medicaid agencies have been submitting files at least monthly to CMS to identify all dually eligible beneficiaries in each State. This includes full-benefit dually eligible individuals and partial-benefit dually eligible individuals. The file is called the ''MMA File'' (after the Medicare Prescription Drug Improvement and Modernization Act of 2003), or State Phasedown File. See here for more information.

SNPs other than those that have MLTSS contracts to operate in the State.

Response: We acknowledge the comments and recognize the concern that some current FIDE SNPs may no longer meet the requirements to be a FIDE SNP. As we described at 87 FR 1865 through 1866, our analysis found that if our proposed changes went into effect, relatively few FIDE SNPs would lose FIDE SNP distinction. D–SNPs that do not meet the proposed FIDE SNP definition at § 422.2 may still meet the HIDE SNP definition at § 422.2, which we are also updating in this rulemaking. In addition, coordination-only D–SNPs remain permissible, which means that States have flexibility in permitting various types of D–SNPs with different levels of integration and coordination with the States' Medicaid managed care programs. We believe the benefits of our proposed changes outweigh the benefit of continuing to allow FIDE SNP designation for plans that do not have the level of integration achieved by the same legal entity covering Medicare Part A and Part B benefits (subject to limited exclusions required by the Medicare statute) and comprehensive Medicaid benefits as outlined in our proposal. Further, we acknowledge that States may take different pathways toward integrated care, and we believe the proposed change preserves flexibility for States.

Comment: A commenter requested clarification on how States would conform to the changes to the FIDE SNP definition. Another commenter requested clarification on what would happen if a State refused to clarify their State Medicaid agency contract. The commenter also requested clarification on how and whether dental benefits would be considered under this proposal as some State Medicaid programs cover limited dental benefits.

Response: We appreciate the requests for clarification. As proposed and finalized, the amendments to paragraph (2) of the definition of FIDE SNP will require the Medicaid MCO affiliated with the FIDE SNP to cover specified Medicaid benefits under a capitated contract under section 1903(m) of the Act. For contract year 2023 and 2024, the required Medicaid-covered benefits are all primary and acute care benefits and long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, which is consistent with the current regulation and practice (because we currently permit a complete carve-out of Medicaid behavioral health benefits). Beginning with contract year 2025, the required Medicaid-covered benefits are all primary and acute care benefits (including Medicare cost-sharing for Medicare Part A and Part B benefits), long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, Medicaid home health (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and Medicaid behavioral health services. We expect that States that wish to have FIDE SNPs operate in their State will review and, as necessary, update their MCO Medicaid managed care contracts to include this full scope of services for the necessary time periods.

If the FIDE SNP's MCO contract with the State Medicaid agency does not cover the required scope of Medicaid benefits, the MA organization could still offer a HIDE SNP, as defined at § 422.2, or a coordination-only D–SNP. Under the proposed regulation, CMS is not requiring the FIDE SNP to cover Medicaid dental benefits in order to meet the definition of FIDE SNP, but States may choose to include dental benefits in their Medicaid MCO contract with a FIDE SNP.

Comment: A commenter urged CMS to exercise the appropriate oversight to ensure that D–SNP enrollees have access to the full range of Medicare benefits for which they are eligible, and that D–SNPs adhere to Medicare requirements for access to medically necessary services. The commenter stated that MA plans have limited understanding of Medicare benefit and coverage criteria, leading to inappropriate denials of medically necessary care for vulnerable enrollees. The commenter urged CMS to (1) develop and implement a regulatory mechanism to ensure plan compliance with MA requirements, and (2) allow State Medicaid agencies greater authority over the operations of D–SNPs on the level of care determinations and access to medically necessary services, for example, by including certain reporting requirements in State contracts and using that information in public reporting and when establishing ongoing agreements.

Response: We appreciate the comment. CMS conducts regular program audits of MA plans to assess compliance with Medicare Advantage requirements, which include coverage of almost all Medicare Part A and Part B benefits. As discussed in the proposed rule (87 FR 1869), section 164(c)(4) of MIPPA does not require a State to enter into a contract with an MA organization with respect to a D–SNP (as described in section 1859(b)(6)(B)(ii) of the Act), which therefore provides States with significant control over the availability of D–SNPs in their markets. The State's discretion to contract with D–SNPs, combined with the State's control over its Medicaid program, creates flexibility to require greater integration of Medicare and Medicaid benefits from the D–SNPs that operate in the State. States have broad authority to include specific requirements for D–SNPs in their State Medicaid agency contracts (and some States currently do so). We believe that State Medicaid agencies have sufficient oversight authority over the operations of D–SNP plans and flexibility to allow States to require that MA organizations provide reports to the States under the State Medicaid agency contracts so long as such reports and information sharing, and/or specific performance standards are consistent with applicable law and do not violate 42 CFR part 422 requirements. In the proposed rule (87 FR 1869 through 1870), we gave examples of States that require specific care coordination or data sharing activities in their contracts with D–SNPs.

(2) Requiring FIDE SNPs To Cover Medicaid Primary and Acute Care Benefits

Primary and acute care benefits for dually eligible beneficiaries are generally covered by Medicare as the primary payer rather than Medicaid. We proposed revisions to the FIDE SNP definition in paragraph (2)(i) of § 422.2 to limit the FIDE SNP designation to D–SNPs that cover primary care and acute care services and Medicare cost-sharing—to the extent such benefits are covered for dually eligible individuals in the State Medicaid program—through their capitated contracts with State Medicaid agencies. As described in the proposed rule (87 FR 1864), we proposed that this requirement would mean that all primary and acute care services, including the Medicare cost-sharing covered by the State Medicaid program (as discussed and finalized for 2025 in section II.A.5.b. of this final rule) must be covered by the FIDE SNP under the MCO contract between the State and the organization that offers the FIDE SNP and the MCO; we did not propose any exceptions or mechanism for carving out coverage of primary and acute care. However, we did clarify that Medicaid non-emergency medical transportation (NEMT) as defined in § 431.53 is not a primary or acute care service included in the scope of this provision. We solicited comment on whether we should allow for specific carve-outs of some of these benefits and services. We welcomed specific

examples of primary and acute care benefits that are either currently carved out of FIDE SNP capitated contracts with State Medicaid agencies or should be carved out and requested that comments include the reason for the existing and proposed future carve-outs.

Comment: Several commenters supported CMS's proposed requirement that all primary and acute care benefits must be covered by FIDE SNPs through a capitated contract with the State Medicaid agency.

Response: We thank the commenters for their support.

Comment: A commenter expressed support and agreement with CMS that Medicaid non-emergency medical transportation, while a critical service, should not be considered a primary or acute care service for the purpose of this definition. Other commenters expressed concern about excluding Medicaid NEMT from the services that must be included in a FIDE SNP's contract with a State. A commenter acknowledged that many States cover NEMT benefit through Statewide contracts with an NEMT provider, but believed that in many States NEMT does not work well for beneficiaries, and coordination with doctors and other service providers has been poor. The commenter believed integrating NEMT, if done well, should be able to help address some of those current deficiencies. Other commenters noted that NEMT is vital to ensure dually eligible individuals with transportation barriers have access to the care they need. These commenters cited a preliminary study on NEMT access in the MA program which shows that the use of an NEMT benefit in MA plans is correlated with an average 1.5 times more primary care physician visits than for those beneficiaries who didn't use the benefit.

Response: We appreciate the comments on the inclusion of NEMT. We acknowledge that NEMT is a critical service for dually eligible individuals. We note that our proposal does not preclude States from including NEMT in their contracts with D–SNPs or their Medicaid managed care plans. However, we continue to believe that it is not a primary or acute care service and therefore, NEMT is not required to be included in the Medicaid capitated contract that is necessary for FIDE SNP designation.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, including those in section II.A.5.b., we are finalizing our proposed revisions for paragraph (2)(i) of the definition of a FIDE SNP at § 422.2 with a delay in applicability date until the 2025 plan year for the requirement that FIDE SNPs cover Medicare cost-sharing in their capitated contracts with State Medicaid agencies.

(3) Requiring FIDE SNPs To Cover Medicaid Behavioral Health Services

We described at 87 FR 1865 the need for and importance of behavioral health services among dually eligible individuals. We explained earlier in this section that, consistent with how we were operationalizing the FIDE SNP definition since first adopting it at § 422.2 as established in the April 2011 final rule, we have allowed plans to meet the FIDE SNP definition even where a State excluded Medicaid behavioral health services from the capitated contract with the State Medicaid agency. In the April 2019 final rule, we added behavioral health services to the list of benefits that a D–SNP must cover, consistent with State policy, to obtain the FIDE SNP designation. We stated that complete carve out of behavioral health by a State from the scope of the Medicaid coverage provided by a FIDE SNP would be permissible (84 FR 15706 through 15707). We believe that a revision to that policy is appropriate and proposed to establish in a new paragraph (2)(iii) in the FIDE SNP definition at § 422.2 requiring that, for 2025 and subsequent years, the capitated contract with the State Medicaid agency must include coverage of Medicaid behavioral health services. This proposal would require the Medicaid MCO that is offered by the same entity offering the FIDE SNP to cover all behavioral health services covered by the State Medicaid program for the enrollees in the FIDE SNP. Our proposal to require FIDE SNPs to cover Medicaid behavioral health services is consistent with sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act. We proposed the 2025 date to allow time for MA organizations and States to adapt to our proposal. In addition, we proposed (as discussed in section II.A.5.e. of this final rule) an amendment to § 422.107 to add a new paragraph (h) to adopt a standard for limited exclusions from the scope of Medicaid benefits coverage by FIDE SNPs and HIDE SNPs of certain behavioral health services.

Restricting FIDE SNP designation to D–SNPs that cover Medicaid behavioral health services, as well as other benefits, under a capitated Medicaid MCO contract with the State Medicaid agency has two advantages. First, it better comports with a common understanding of being ''fully integrated''—the term used in sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act—because of the importance of behavioral health services for dually eligible individuals. Second, coverage of Medicaid behavioral health services also facilitates integrating behavioral health and physical health services, which can result in improved outcomes for dually eligible beneficiaries.[35] In addition, our proposal would more clearly distinguish a FIDE SNP—which would have to cover both LTSS and behavioral health services—from a HIDE SNP—which must cover either LTSS or behavioral health services. This would reduce confusion among stakeholders. As we discussed at 87 FR 1865 through 1866, most FIDE SNPs already have contracts with States to cover Medicaid behavioral health benefits, indicating that the market has already moved in this direction and relatively few FIDE SNPs would be impacted by our proposal. We believe the benefit of restricting FIDE SNP designation to plans that cover Medicaid behavioral health services in the capitated contract with the State Medicaid agency outweighs the benefit of continuing to allow FIDE SNP designation for plans that do not cover these benefits. Increasing the minimum scope of services that FIDE SNPs must cover in an integrated fashion is consistent with how section 1859(f)(8)(D) of the Act identifies Medicaid LTSS and behavioral health services as key areas for the integration of services. While the statute generally describes the increased level of integration that is required by referring to coverage of behavioral health or LTSS or both, we believe that exceeding that minimum standard is an appropriate goal for FIDE SNPs. The most integrated D–SNPs—FIDE SNPs—should cover the broadest array of Medicaid-covered services, including the behavioral health treatment and LTSS that are so important to the dually eligible population.

Further, increasing the minimum scope of services for FIDE SNPs is not inconsistent with section 1853(a)(1)(B)(iv) of the Act, which states that such plans are fully integrated with capitated contracts with States for Medicaid benefits, including LTSS. While section 1853(a)(1)(B)(iv) does not specify coverage of behavioral health services, it does not exclude coverage of behavioral health services either given that the section speaks generally to FIDE SNPs having fully integrated contracts with States for Medicaid benefits. As

[35] Medicaid and CHIP Payment and Access Commission. ''Integration of Behavioral and Physical Health Services in Medicaid.'' March 2016. Available at: *https://www.macpac.gov/wp-content/uploads/2016/03/Integration-of-Behavioral-andPhysical-Health-Services-in-Medicaid.pdf.*

discussed at 87 FR 1865, behavioral health services are critical for dually eligible individuals and benefit from coordination with Medicare services and, we believe, coverage of Medicaid behavioral health benefits by a D–SNP is key to achieving fully integrated status.

Comment: Numerous commenters expressed support for CMS's proposal to require FIDE SNPs to cover behavioral health services. Several commenters believed the proposal addresses the intent of the BBA of 2018 to increase Medicare-Medicaid integration. A few commenters stated that behavioral health is a critical component of a fully integrated model of care and that inclusion of behavioral health is essential to providing high-quality, effective care for dually eligible individuals. A commenter stated that issues related to behavioral health and substance use have been exacerbated due to the COVID–19 pandemic, heightening the importance of access to behavioral health and substance use disorder treatment. Several commenters believed that strengthening access to behavioral health services is a growing concern that merits greater attention and that CMS's proposal is an important step in the direction toward improving and protecting access to behavioral health services. A commenter supported the proposal for FIDE SNPs to cover Medicaid behavioral health services along with continued flexibility of allowing some limited carve-outs. A commenter encouraged CMS to require all D–SNPs—not just FIDE SNPs—to cover Medicaid behavioral health services to address misalignment of services for dually eligible individuals with behavioral health diagnoses or addition, but the commenter recognized the proposal as a glide path toward greater integration.

Response: We appreciate the widespread support for our proposal. We agree that requiring FIDE SNPs to cover Medicaid behavioral health services as proposed at paragraph (2)(iii) of the definition of FIDE SNPs in § 422.2 would improve Medicare-Medicaid integration for beneficiaries.

Comment: A few commenters opposed the proposal because States with behavioral health carved out of Medicaid managed care, including California, New York and Pennsylvania, would not be permitted to have FIDE SNPs if the proposal is finalized. A commenter stated that operationalizing this change in Pennsylvania would require legislative action, that a multitude of stakeholder groups would oppose the proposal, and that the current Commonwealth administration would not support the proposal. The commenter noted that there would be no way for the current Pennsylvania FIDE SNPs to meet the proposed CMS requirements beginning in 2025 to maintain their FIDE SNP status.

Another commenter noted that all D–SNPs in Oregon are required to coordinate with all Medicaid benefits, including dental and behavioral health. However, this commenter emphasized that D–SNPs in Oregon would not be able to easily achieve FIDE SNP status because of statutory carve-outs of LTSS. Several commenters requested clarification from CMS to address situations where benefits such as behavioral health or LTSS are carved out at a State level, including California and Pennsylvania, which prevents D–SNPs from receiving the HIDE SNP and FIDE SNP designation despite meeting other criteria. A commenter explained that some States believe a specialty behavioral health plan with a focused suite of intense services on the highest utilizers to improve outcomes among people with serious mental illness is the most effective way to decrease health care costs and improve quality. The commenter stated that, should D–SNPs in those States lose the ability to receive the HIDE SNP and FIDE SNP designation, it would result in the loss of flexibilities, such as the frailty adjustment, which could limit the D–SNPs' ability to provide complete care and supplemental benefits to their enrollees. To assist with any implementation of this provision, the commenter asked that CMS provide further clarification on the effect of this provision in States where a carve-out exists.

Response: We appreciate the perspective raised by these commenters. We recognize that not all States currently include Medicaid behavioral health and Medicaid LTSS benefits in their capitated Medicaid contracts. We believe the advantages of restricting FIDE SNP designation to plans that cover behavioral health and Medicaid LTSS benefits in the capitated contract with the State Medicaid agency outweigh the advantages of continuing to allow FIDE SNP designation for plans that do not cover these benefits. As stated in the proposed rule, increasing the minimum scope of services that FIDE SNPs must cover in an integrated fashion is consistent with how section 1859(f)(8)(D) of the Act identifies Medicaid LTSS and behavioral health services as key areas for the integration of services. While the statute generally describes the increased level of integration that is required by referring to coverage of behavioral health or LTSS or both, we believe that exceeding that minimum standard is an appropriate goal for FIDE SNPs. The most integrated D–SNPs—FIDE SNPs— should cover the broadest array of Medicaid-covered services, including the behavioral health treatment and LTSS that are so important to the dually eligible population. As we discussed in the proposed rule (87 FR 1866), based on a New York State Medicaid policy change, we expect FIDE SNPs in New York to cover Medicaid behavioral health services effective January 1, 2023, so we do not anticipate our proposal will negatively impact FIDE SNPs in New York. If other States choose to keep behavioral health carved out of their SNP contracts, the remaining FIDE SNPs in those States would not meet the new requirements for FIDE SNPs that we are finalizing in the definition at § 422.2. Such plans may still meet the HIDE SNP definition at § 422.2, which we are also revising in this rulemaking.

Comment: Some commenters expressed concern about continuity and quality of care with behavioral health being carved into FIDE SNPs. A few commenters supported the provision to require FIDE SNPs cover behavioral health, but cautioned that CMS should require strong steps to avoid disruption in behavioral health care when transitioning individuals in the 24 FIDE SNPs that do not currently have behavioral health in their contracts. A commenter highlighted the importance of consistency, continuity, and ongoing access to trusted providers in behavioral health, and that even small disruptions in provider networks or changes in procedures to access providers can set back progress for affected beneficiaries.

A commenter urged CMS to consider, when approving carve-ins of behavioral health in any D–SNP, the importance of ensuring that the move does not degrade the quality of care. The commenter shared the following example: Some county systems have experience in behavioral health for persons with serious mental illness that is difficult to duplicate. In some jurisdictions, carved-out behavioral service systems, which serve many individuals who are homeless or in danger of homelessness, are closely integrated with housing service providers, working together to bring stability to this high need population. This commenter stated that, in the States where behavioral services were integrated into the FAI demonstrations, the path was often rocky, particularly where plan sponsors had little experience in the area.

Another commenter believed that the agencies with which States contract to provide behavioral health services often

provide inadequate support for individuals needing behavioral health treatment facilities and do not assist with finding community providers.

Response: We appreciate the comments and agree that continuity of care is important for enrollees receiving behavioral health care treatment and the valuable care and supports delivered by behavioral health providers who operating outside of FIDE SNPs. However, our proposal to require FIDE SNPs to cover Medicaid LTSS and Medicaid behavioral health services would not require any enrollees to transition from their current D–SNPs, nor would it require a State to carve-in behavioral health services. If the 24 FIDE SNPs do not meet the proposed FIDE SNP definition at § 422.2 due to a behavioral health carve-out in 2025, they may still meet the HIDE SNP definition at § 422.2 or the definition of a coordination-only D–SNP; therefore, enrollees could remain in these MA plans without disruption. In addition, States have the ability to establish linkages between behavioral health providers and D–SNPs to facilitate coordination of care if the State believes that is preferable to including such behavioral health services in the Medicaid MCO contract held by the FIDE SNP (or a less comprehensive Medicaid managed care contract held by a HIDE SNP). If States decide to carve in behavioral health services into FIDE SNPs or other D–SNPs, they can work with the plans and providers to ensure existing delivery systems for behavioral health are not disrupted.

While we proposed to allow limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNP, as discussed in II.A.5.e., we clarify that we did not propose to establish requirements related to approving a State's decision to include certain services in their Medicaid programs. Our proposal, and the provisions finalized on this point in this rule, are specific to the minimum standards we believe are necessary for an MA plan to be designated as a fully integrated or highly integrated special needs plan for dually eligible individuals.

In addition, if a State newly includes Medicaid LTSS and/or Medicaid behavioral health services into its contract with a D–SNP, the D–SNPs must ensure continuity of care and integration of services, including with community programs and social services, as described at § 422.112(b). This requirement applies to all MA plans, including all types of D–SNPs.

Comment: A commenter expressed appreciation for the delayed effective date of 2025 but also suggested considering a longer timeframe for compliance or additional temporary exclusions from the scope of Medicaid coverage required for FIDE SNPs to allow for transitions. Another commenter urged CMS to consider allowing an extended timeframe beyond 2025 for States that demonstrate commitment to integrating behavioral health services in FIDE SNPs to account for the State's procurement strategy, demonstrate commitment to developing or refining a FIDE SNP model to integrate care for dually eligible individuals, or demonstrate a commitment to designing a State-specific solution to fully coordinate behavioral health services with all Medicare and Medicaid benefits that results in seamless coverage. The commenter requested that CMS offer supports to States that currently carve out behavioral health but wish to pursue more integrated models of care for dually eligible individuals, including technical assistance, additional resources for identifying the most appropriate pathway for carving behavioral health benefits into FIDE SNPs or more generally to Medicaid managed care contracts.

Response: We thank the commenters and appreciate their perspectives. We appreciate that States will have different pathways and considerations for including Medicaid behavioral health services in the MCO contracts held by FIDE SNPs by 2025, but we do not agree with extending the timeline. As we discuss in the proposed rule (87 FR 1865 through 1866), our review of State Medicaid agency contracts for FIDE SNPs in contract year 2021 indicates that States include full coverage of Medicaid behavioral health services for most FIDE SNPs (45 of the 69 FIDE SNPs) and policy changes in New York to be effective in 2023 will increase this number. If the remaining FIDE SNPs in California and Pennsylvania do not meet the additional requirements we proposed and are finalizing as part of the FIDE SNP definition at § 422.2, these plans may still meet the requirements to be a HIDE SNP, consistent with the revised definition that we proposed and are finalizing in this rule at § 422.2. We believe the benefit of restricting FIDE SNP designation to plans that cover Medicaid behavioral health services in the capitated contract with the State Medicaid agency outweigh the benefit of continuing to allow FIDE SNP designation for plans that do not cover these benefits.

We are available to assist States interested in pursuing more integrated models of care for dually eligible individuals, and we are actively planning for upcoming technical assistance opportunities.

Comment: A commenter highlighted the benefits of the behavioral health carve-out model used in Pennsylvania, in which a wide variety of behavioral health services are delivered through a specialized Mental Health and Substance Use Disorder provider network. The commenter stated that the carve-out model implements evidence-based and promising practices in the area of behavioral health, ensures a single point of accountability, better utilization management of services, and overall better management of costs while ensuring improved outcomes for the individuals served.

The commenter did not agree with CMS's logic that FIDE SNPs have an incentive to steer beneficiaries toward behavioral health Medicaid covered services for which they are not financially responsible. The commenter wrote that, since Medicaid is always the payor of last resort, if the service is a covered Medicare service, Medicare would be the primary payor.

The commenter also believes it is possible that changes in the health of enrollees or changes in membership over time could change a FIDE SNP's population mix to the point that it would impact their frailty score and thus make them eligible for the increased revenue from the frailty adjustment. The commenter expects this issue concerning potential future frailty adjustment payments would create pushback from current FIDE SNPs in Pennsylvania if they no longer qualify as FIDE SNPs.

Response: We appreciate that, in Pennsylvania and other States, policymakers may prefer to maintain existing delivery systems for behavioral health rather than to include those services in the MCO contracts held by FIDE SNPs. In those States, current FIDE SNPs would be re-designated as HIDE SNPs in 2025 and thus be ineligible for the frailty adjustment, even if the level of frailty in those D–SNPs would otherwise qualify the plan for frailty adjustment. That is a downside to our proposal but we do not believe it outweighs the other benefits outlined here of limiting FIDE SNP designation to plans that cover Medicaid behavioral health services, subject to minimal exclusions that CMS has approved under proposed § 422.107(h) (which is discussed and finalized in section II.A.5.e. of this final rule).

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed revisions for paragraph (2)(iii) of the definition of a FIDE SNP at § 422.2 without modification.

(4) Requiring FIDE SNPs To Cover Medicaid Home Health and Medical Supplies, Equipment, and Appliances

We proposed to require that, effective beginning in 2025, each FIDE SNP must cover additional Medicaid benefits to the full extent that those benefits are covered by the State Medicaid program. Two categories of Medicaid benefits we proposed to add include home health services, as defined in § 440.70, and medical supplies, equipment, and appliances, as described in § 440.70(b)(3). We believe that FIDE SNPs should be required to cover the Medicaid home health benefits and medical supplies, equipment, and appliances (to the full extent these benefits are covered by Medicaid) because both are critical services for dually eligible individuals, necessitate coordination due to being covered by both the Medicare and Medicaid programs, and are not clearly captured under other parts of the existing definition. Based on our review of State coverage requirements for Medicaid MCOs affiliated with FIDE SNPs, all current FIDE SNPs already cover Medicaid home health services and medical supplies, equipment, and appliances, so we did not expect our proposal to impact any existing FIDE SNPs. However, we proposed that this change in the scope of required coverage by FIDE SNPs would not apply until 2025 in case there were other circumstances of which we were not aware that would necessitate additional time to adapt to our proposal.

As such, we proposed to add new paragraphs (2)(iv) and 2(v) to the FIDE SNP definition at § 422.2 to require that the capitated contract between the State Medicaid agency and the legal entity that offers the FIDE SNP must include Medicaid home health services as defined at § 440.70 and Medicaid DME as defined at § 440.70(b)(3). In this final rule, we are correcting the terminology to use the phrase ''medical equipment, supplies, and appliances'' to better track the regulation text at § 440.70(b)(3). As described in the proposed rule (87 FR 1864), we proposed that this new requirement would mean that all Medicaid benefits in these categories would be covered by the MCO that is affiliated with the FIDE SNP, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in the FIDE SNP, and we did not propose any exceptions. Because the same legal entity must have the MA contract with CMS for the D–SNP and the Medicaid MCO contract with the State and the enrollment in the FIDE SNP must be limited to dually eligible individuals who are also enrolled in the MCO, this entity is functionally all the FIDE SNP.

Comment: A number of commenters expressed support for CMS's proposal to require FIDE SNPs to cover Medicaid home health and DME under their Medicaid MCO contracts. Several commenters noted that home health services and DME are critical services for dually eligible individuals. A commenter noted that home health is important because it curtails the need for more expensive health care options such as emergency room visits, hospital readmissions, and skilled nursing facility stays. The commenter also stated that DME benefits are important as they can assist with mobility and independence for beneficiaries and therefore improve quality of life. Several commenters highlighted that beneficiaries have long faced complex barriers to acquiring certain DME. A commenter noted that the proposal addresses the intent of the BBA of 2018 to increase Medicare-Medicaid integration. A commenter expressed their support and noted that D–SNP State Medicaid agency contracts in Arizona already conform to CMS's proposed definition.

Several commenters agreed with CMS that 2025 implementation is appropriate in case any unforeseen issues arise. A few commenters suggested that the requirement for integration of home health and DME go into effect immediately rather than waiting until 2025.

Response: We appreciate the widespread support of our proposal that FIDE SNPs must cover Medicaid home health and DME under their Medicaid MCO contracts. We agree with commenters who stated that accessing DME (that is, medical equipment, supplies, and appliances) can be a challenge for beneficiaries, and we believe this proposal is a step towards addressing that issue. While a few commenters questioned if it is necessary to wait until 2025 to implement the proposal, we believe waiting until 2025 to require coverage will allow adequate time to adapt to any unforeseen circumstances that may arise and will not cause loss of any integration in current FIDE SNPs that already cover Medicaid home health services and DME.

Comment: A commenter stated that States will need to ensure that D–SNPs understand the details of Medicaid coverage of the required services to ensure that enrollees receive the full extent of benefits they are currently eligible to receive under Medicaid. This will require State oversight and reporting by D–SNPs to the State.

Response: We thank the commenter. As proposed and finalized, this new requirement for FIDE SNPs must be met through the Medicaid MCO contract held by the legal entity that offers both the FIDE SNP and the Medicaid MCO. We anticipate that the Medicaid MCO contract addresses reporting by the entity (as would any Medicaid managed care contract whether associated with a HIDE SNP or coordination-only D–SNP or not) to the State and oversight by the State over Medicaid benefit delivery and administration. Medicaid managed care regulations, such as § 438.66, require States to monitor their Medicaid managed care programs. Further, under current regulation at § 422.107(c)(1), the State Medicaid agency contract must document the D–SNP's responsibility to coordinate the delivery of Medicaid benefits for its enrollees. States and D–SNPs should already be communicating related to Medicaid benefits. This communication will be important to successful implementation of this final rule.

Comment: A commenter supported the proposal to require that FIDE SNPs cover Medicaid home health services and DME as defined in § 440.70(b)(3) but recommended a modification. The commenter highlighted that the terminology used in § 440.70(b)(3) is ''medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place.'' The commenter recommended that CMS require FIDE SNPs to cover ''medical supplies, equipment and appliances'' as referenced in that subsection to ensure that the regulation is not interpreted to require coverage of only a subset of that category of services. The commenter believed that allowing nurse practitioners to order and certify Medicare and Medicaid home health services, and Medicaid medical supplies, equipment and appliances for their patients, as authorized in the CARES Act, has been integral to patients receiving medically necessary services in a timely fashion.

Response: We appreciate the commenter's support and suggestion. We believe that it is important to utilize the prevailing Federal definitions for Medicaid services and therefore will use the terminology in § 440.70(b)(3),

''medical supplies, equipment, and appliances,'' along with the reference to § 440.70(b)(3), in the new paragraph (2)(v) of the FIDE SNP definition at § 422.2 to clearly identify the mandatory scope of coverage.

Comment: A commenter stated that the current Puerto Rico D–SNP program offered with the local government, Platino, is fully coordinated but the D–SNPs do not cover certain LTSS and nursing home services because Congress chose not to provide funding to Puerto Rico for these Medicaid services. The commenter urged CMS to allow plans in Puerto Rico to be eligible as FIDE SNPs and receive the frailty adjustment even though those D–SNPs do not cover these benefits.

Response: We appreciate the comment about Puerto Rico's Medicaid program and understand the lack of Medicaid long term care benefits in Puerto Rico prevents D–SNPs in Puerto Rico from meeting the FIDE SNP requirements. As a result, no D–SNPs in Puerto Rico currently meet the requirements to be a FIDE SNP, and this rulemaking does not change those circumstances.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed revisions in paragraph (2)(iv) of the definition of FIDE SNP at § 422.2. We are finalizing paragraph (2)(v) of the FIDE SNP definition with a technical change to clarify that for plan year 2025 and subsequent years, the Medicaid capitated contract required for a FIDE SNP must cover medical supplies, equipment, and appliances as described in § 440.70(b)(3).

d. Clarification of Coverage of Certain Medicaid Services by HIDE SNPs

CMS first defined the term ''highly integrated dual eligible special needs plan'', or HIDE SNP, at § 422.2 in the April 2019 final rule. As currently defined at § 422.2, a HIDE SNP is a type of D–SNP offered by an MA organization that has—or whose parent organization or another entity that is owned and controlled by its parent organization has—a capitated contract with the Medicaid agency in the State in which the D–SNP operates that includes coverage of Medicaid LTSS, Medicaid behavioral health services, or both, consistent with State policy. As stated in the April 2019 final rule (84 FR 15705), the HIDE SNP designation is consistent with section 1859(f)(8)(D)(i)(II) of the Act that recognizes a level of integration that does not meet the requirements of the FIDE SNP with respect to the breadth of services provided under a Medicaid capitated contract with the State.

We proposed to revise the HIDE SNP definition at § 422.2 consistent with proposed changes to the FIDE SNP definition described earlier in section II.A.5.c. of this final rule to more clearly outline the services HIDE SNPs must include in their contracts with State Medicaid agencies. Similar to our proposal for the revised FIDE SNP definition, we proposed to move away from the current use of ''coverage, consistent with State policy'' language in favor of more clearly articulating the minimum scope of Medicaid services that must be covered by a HIDE SNP by using the phrase ''to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State.'' In section II.A.5.e. of this final rule, we also discuss our proposal to adopt new provisions in § 422.107 to permit limited carve-outs from the required scope of services.

Later in this section, we describe our proposal to require that the capitated Medicaid contract applies in the entire service area for the D–SNP in more detail. Otherwise, our proposal was generally a reorganization and clarification of the scope of Medicaid benefits that must be covered by a HIDE SNP.

Comment: Numerous commenters supported CMS's proposal for HIDE SNPs to be required to cover the vast majority of Medicaid behavioral health services or the vast majority of Medicaid LTSS. MACPAC expressed support for CMS's proposed changes to the HIDE SNP definition because the proposed change would further integration and clarify the definitions of these plans. Several other commenters supported the proposal and believed that it would further clarify the distinction between HIDE SNP and FIDE SNP coverage requirements. A commenter expressed support because they believed that there has been a significant lack of clarity and comprehension around HIDE SNP definitions, and, in general, what can be expected of particular types of SNPs. Another commenter expected that the proposal would reduce confusion, provide more transparency of State Medicaid agency contract review, and allow continued flexibility for D–SNPs to provide either LTSS or behavioral health services. Another commenter expressed support because CMS's proposal maintains flexibility for States to leverage integrated plans even if they cannot meet all the requirements for FIDE SNPs.

Response: We appreciate the numerous comments of support for our proposal to revise the definition of HIDE SNPs at § 422.2. We agree that these changes, as proposed and finalized in this rule, and in conjunction with the proposed changes to § 422.107(g) and (h), will clarify the scope of responsibilities for HIDE SNPs, better distinguish them from FIDE SNPs and coordination-only D–SNPs, and provide flexibility to States in how they use D–SNPs in connection with their Medicaid programs.

Comment: A commenter expressed concern that the proposed revisions may not adequately account for variation in State approaches to Medicaid managed care. The commenter recommended CMS reconsider limiting the HIDE SNP definition to the extent that it would disqualify otherwise integrated agreements. The commenter believed the proposed changes only serve to complicate administration, particularly if States with carve-outs beyond the proposed limits were required to pivot to coordination-only agreements to preserve D–SNPs.

Another commenter recommended that CMS permit a HIDE SNP with a Medicaid MCO contract that covers behavioral health services to operate, without requiring the contract to include LTSS. The commenter also suggested that CMS clarify that a HIDE SNP with a State Medicaid agency contract that includes Medicaid services, including behavioral health, does not need to also have separate Medicaid MCO contract.

Response: While we appreciate the commenters' perspectives, we believe that the HIDE SNP designation should be consistent with a high level of integration in which the vast majority of Medicaid LTSS or the vast majority of Medicaid behavioral health services are covered by the capitated contract with the State. These proposed changes are consistent with our proposal to amend the FIDE SNP definition described in section II.A.5.c. to more clearly outline the services integrated D–SNPs, meaning both FIDE SNPs and HIDE SNPs, must include in their contracts with State Medicaid agencies. We clarify that if the MA organization offering a D–SNP—or the MA organization's parent organization, or another entity that is owned and controlled by its parent organization—has a Medicaid managed care contract with the State that includes coverage of Medicaid behavioral health benefits but excludes coverage of Medicaid LTSS, the MA organization may qualify as a HIDE SNP provided other applicable requirements (such as a compliant

Medicaid State agency contract, as required by § 422.107 and, beginning January 1, 2025, minimum service area requirements) are met. We further clarify that the HIDE SNP definition, either currently or as amended in this final rule, does not require the affiliated Medicaid plan to be an MCO contract, it could be a PAHP or PIHP; Medicaid managed care regulations in 42 CFR part 438 establish the requirements for a managed care contract (that is, a capitated contract) for coverage of Medicaid benefits.

Comment: A few commenters requested clarification on whether these provisions limit HIDE SNP enrollments to exclusively aligned enrollment. A commenter noted that while they support greater clarification around alignment for HIDE SNPs, they recognized the challenges of exclusively aligned enrollment and that States may need to contract with D–SNPs in ways that promote integration but also allow States to design programs that meet their specific needs and fit within the parameters of current State benefit offerings. The commenter believed additional clarity may be helpful in defining alignment options for HIDE SNPs.

Response: We welcome the opportunity to clarify our proposal. We clarify that HIDE SNP plans are not required to have exclusively aligned enrollment. Please see the discussion in section II.A.5.f. for more detail about our proposal to require the capitated contract in the entire service area for the D–SNP.

Comment: Some commenters requested that CMS apply the frailty adjustment to all highly integrated products, including HIDE SNPs. A few commenters specifically encouraged CMS to allow HIDE SNPs that provide LTSS to be eligible for the frailty adjustment. Several commenters noted that there are strong similarities between enrollees in HIDE SNPs and FIDE SNPs, and since both plan types serve enrollees that are generally frailer than the typical Medicare population, both should be eligible to receive higher adjustment payments if they have a similar average frailty as the PACE program. A commenter stated that allowing HIDE SNPs to receive the frailty adjustment would more appropriately apply the frailty adjustment to integrated plans serving people dually eligible for both Medicare and Medicaid, while acknowledging State contracting differences. A few commenters stated that allowing HIDE SNPs to receive the frailty adjustment would make the HIDE SNP market more competitive or incentivize further integration of plans.

Response: We appreciate the comments regarding the frailty adjustment provided by section 1853(a)(1)(B)(iv) of the Act; however, they are beyond the scope of this rulemaking.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed revisions for the definition of a HIDE SNP at § 422.2 without modification.

e. Medicaid Carve-Outs and FIDE SNP and HIDE SNP Status

As discussed earlier, we proposed to require FIDE SNPs and HIDE SNPs to cover the full scope of the Medicaid coverage under the State Medicaid program of the categories of services that are specified as minimum requirements for these plans as outlined in sections II.A.5.c. and II.A.5.d. We also proposed that coverage of the full scope of the specified categories of Medicaid benefits is subject to an exception that may be permitted by CMS under § 422.107(g) or (h). We proposed to codify at § 422.107(g) and (h), respectively, current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs. As discussed in section II.A.5.c.1. of this final rule, CMS has historically determined D–SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, LTSS, and behavioral health services from the Medicaid coverage furnished by the MCO offered by the FIDE SNP. CMS has similarly permitted carve-outs of the scope of Medicaid coverage furnished in connection with HIDE SNPs. We believe that codifying these policies permitting exclusions from the scope of Medicaid behavioral health and Medicaid LTSS would improve transparency for stakeholders and allow us to better enforce our policies to limit benefit carve-outs. We did not propose to permit exclusions from coverage of Medicaid primary care or acute care for FIDE SNPs.

Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020,[36] with some revisions to improve clarity and avoid misinterpretations of our policy that might result from language in the memorandum that differs in the allowed carve-outs for LTSS and behavioral health services. Like the memorandum, our proposal was designed to accommodate differences in State Medicaid policy—for example, the desire to retain delivery through the Medicaid FFS program of specific waiver services applicable to a small, specified population, or to retain coverage in the Medicaid FFS program for specific providers—without significantly undermining the level of Medicaid integration provided by HIDE SNPs and FIDE SNPs. While we generally favor integration and worry that Medicaid benefit carve-outs work against integration, we believe our proposal strikes a balance between the current realities of State Medicaid managed care policy, applicable statutory provisions, and our implementation of those statutory provisions toward the goal of raising the bar on integration.

Currently and under our proposal to revise the definition, a D–SNP may meet the criteria for designation as a HIDE SNP if it covers either Medicaid LTSS or Medicaid behavioral health services under a State Medicaid agency contract. We currently grant HIDE and FIDE SNP status despite Medicaid LTSS carve-outs of limited scope if such carve-outs (1) apply to a minority of the full-benefit dually eligible LTSS users eligible to enroll in a HIDE or FIDE SNP who use long-term services and supports or (2) constitute a small part of the total scope of Medicaid LTSS provided to the majority of full-benefit dually eligible individuals eligible to enroll in a HIDE or FIDE SNP who use Medicaid LTSS. We provided examples of permissible LTSS carve-outs at 87 FR 1867. D–SNPs can currently obtain the HIDE or FIDE SNP designation with limited carve-outs of Medicaid behavioral health services from their capitated contracts. A behavioral health service carve-out would be of limited scope if such a carve-out (that is, exclusion from coverage by the Medicaid managed care plan affiliated with the D–SNP): (1) Applies primarily to a minority of the full-benefit dually eligible users of behavioral health services eligible to enroll in a HIDE or FIDE SNP; or (2) constitutes a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in a HIDE or FIDE SNP. We specified that only a small part of the Medicaid behavioral health services may be carved out in order to ensure that the innovative services that many

[36] CMS, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'', January 17, 2020. Retrieved from: *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5*.

Medicaid programs provide to individuals with severe and moderate mental illness are covered through the D–SNP (through the MA organization's Medicaid managed care capitated contract) or the affiliated Medicaid managed care plan (through the Medicaid managed care capitated contract with the MA organization's parent organization or another entity that is owned or controlled by the parent organization). We believe that level of integrated coverage is a minimum standard for a D–SNP to be considered highly or fully integrated. We provided examples of permissible LTSS carve-outs at 87 FR 1868.

We described our intent to administer this proposed regulation consistent with our current policy and therefore anticipated little disruption to occur because of this proposed change.

Comment: Numerous commenters supported the codification of current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs. Several commenters agreed with CMS that limited or narrow carve-outs of LTSS and behavioral health services are essential given the wide variation in how States choose to provide those services. Another commenter suggested the refined definitions of FIDE and HIDE SNPs could encourage States to carve in LTSS for individuals who need the services the most. Another commenter recognized that the proposed revisions to the HIDE SNP and FIDE SNP definitions are intended to enhance the level of integration in such plans.

Response: We appreciate the widespread support we received for our proposal. While we generally favor integration and worry that Medicaid benefit carve-outs work against integration, we believe our proposal strikes a balance between the current realities of State managed care policy, applicable statutory provisions, and our current implementation of those statutory provisions toward the goal of raising the bar on integration. Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020, and we believe that these revisions will improve clarity and avoid misinterpretations of our policy that might result from language in the memorandum that differs in the allowed carve-outs for Medicaid LTSS and behavioral health services. We agree with commenters that monitoring the impact of carve-outs for impacts on enrollees' access to services and care coordination processes is important.

Comment: A commenter recommended that CMS standardize Medicaid benefit carve-out requirements for States implementing a FIDE SNP model. The commenter further suggested that CMS set rules for how many benefit carve-outs States will be allowed, whether the carve-outs include benefits that do not qualify as primary and acute care services (for example, non-emergency transportation), and how the carve-outs would integrate operationally with the FIDE SNPs if the underlying benefit is handled by a delegated vendor.

Response: We thank the commenter for their perspectives. However, we do not believe it is feasible to establish a uniform set of carve-out limits or a numerical limit on carve-outs due to the variation across States. The requirements we are finalizing at § 422.107(g) and (h) permit only limited carve-outs from the Medicaid LTSS and Medicaid behavioral health services coverage that HIDE SNPs and FIDE SNPs must have included in their managed care contract with the State Medicaid agency. We will apply this evaluation looking at coverage of Medicaid LTSS benefits and/or Medicaid behavioral health services as a whole in connection with the scope of coverage in the Medicaid managed care contract affiliated with the FIDE SNP or HIDE SNP. While the limits in the regulations we are adopting do not equate to or specify how many Medicaid LTSS and/or Medicaid behavioral health services carve-outs a State may have, it does act as a substantive limit when we make determinations that a D–SNP qualifies as a FIDE SNP or HIDE SNP.

The finalized paragraph (2)(i) of the FIDE SNP definition at § 422.2 (discussed earlier in sections II.A.5.c. of this final rule) requires each FIDE SNP to cover primary and acute care services, including Medicare cost-sharing covered by the State Medicaid program as of 2025, under the MCO contract between the State and the organization that offers the FIDE SNP. We did not propose and are not adopting any exceptions or permissible carve-outs for this required coverage. We solicited comment on whether we should allow for specific carve-outs of some primary and acute care benefits and welcomed examples of such benefits that are either currently carved out of FIDE SNP capitated contracts with State Medicaid agencies or should be carved out. We did not receive any comments in response to this solicitation and are finalizing our proposal without modification. We stated in section II.A.5.c. that Medicaid NEMT as defined in § 431.53 is not a primary or acute care service included in the scope of this provision, but that goes to identifying the scope of acute and primary care services, not establishing permissible carve outs for categories of acute and primary care services.

Comment: Another commenter believed carve-outs interfere with true integration but indicated that some Medicaid services may have, historically, not been provided appropriately by managed care plans. The commenter suggested that a State carve-out may be necessary to ensure that enrollees have access to the care they need and recommended that CMS work closely with States to determine why certain carve-outs exist and what the impact may be on access to care if the carve-outs are eliminated. Another commenter stated that the application of a carve-out to a minority of enrollees has less of an impact on individuals needing Medicaid LTSS services and behavioral health services, and several commenters advocated that States should monitor the impact of any service carve-out on enrollees and their quality of care and life.

Response: We thank the commenters and appreciate their perspectives. We agree that monitoring and oversight of carve-outs is important and will work with States to ensure quality of care is not compromised and enrollees are educated about changes to the scope of benefits available through a HIDE SNP or FIDE SNP, particularly in the case of Medicaid LTSS and behavioral health services. We clarify that our proposal would not require that States carve in benefits if they prefer not to do so because MA program regulations permit a D–SNP to be offered without the MA organization (or its parent organization or an entity also owned by its parent organization) having a capitated contract for coverage of Medicaid behavioral health or LTSS benefits. As proposed and finalized, § 422.107(g) and (h) are specific to the required scope of coverage of Medicaid benefits by FIDE SNPs and HIDE SNPs with regard to behavioral health and LTSS benefits.

Comment: A commenter provided an example whereby beneficiaries who may consider enrolling in plans with carve-outs are notified that the integrated services do not include Medicaid LTSS and/or behavioral health services to the extent they are carved-out.

Response: We appreciate this comment and example. Per § 422.2267(e)(5)(ii)(D), all D–SNPs must clearly state which services are included in their plan benefit packages, including

Medicaid benefits, by either including the description in the required summary of benefits or putting the description in a separate document that is provided to enrollees with the summary of benefits. In addition, § 422.111 requires annual disclosures by all MA plans, including D–SNPs, of the scope of and rules for coverage under the plan.

Comment: Another commenter supported full integration and described experience with State carve-outs of Medicaid behavioral health and LTSS services, which the commenter indicated prevents D–SNPs from receiving the HIDE SNP and FIDE SNP designation. The commenter suggested addressing the needs of the dually eligible population which may require specialized programs and tailored methods to support recovery-oriented systems of care.

Response: We thank the commenter and agree that addressing the needs of the dually eligible population is vital for improving health outcomes and is greatly facilitated when the broadest scope of Medicaid behavioral health and LTSS services are integrated into HIDE SNP and FIDE SNP benefit packages.

Comment: Several commenters requested guidance and technical assistance in various areas. A commenter suggested guidance to States to promote interoperability and data sharing between plans specifically when a benefit is carved out. Another commenter suggested CMS provide guidance to States on how to implement a model of care that allows for complete integration.

Response: We thank the commenters and appreciate these suggestions. We anticipate offering technical assistance and providing sub-regulatory guidance based on this final rule.

Comment: Several commenters requested clarification on what is meant by ''a minority of beneficiaries eligible to enroll'' and ''small part of the total scope of services'' as those phrases are used in proposed § 422.107(g) and (h). These commenters suggested that CMS provide additional examples or further description of the review process that would be utilized to make these determinations.

Response: We appreciate the commenters' desire for additional clarification. We believe the examples we provided in the proposed rule at 87 FR 1867 through 1868 are instructive of the type of Medicaid LTSS and behavioral health carve-outs we would permit under § 422.107(g) and (h). We prefer to not inadvertently limit the terms ''minority of beneficiaries eligible to enroll'' or ''small part of the total scope of services'' by providing additional examples, given the potential variation across States. We determine the integration status for MA organizations offering D–SNPs through our annual review of State Medicaid agency contracts (that is, the contracts between States and D–SNPs required by § 422.107) in July. As part of that review, we will assess the scope of existing or proposed carve-outs against the §§ 422.2 and 422.107(g) and (h) requirements and determine whether a D–SNP meets the FIDE SNP or HIDE SNP designation. Where the State Medicaid agency contract is a separate contract from the Medicaid MCO contract, we may review the Medicaid MCO contract available on the State Medicaid agency's website when that is necessary to our evaluation. We strongly encourage States and MA organizations to seek technical assistance from CMS as necessary. As the scope of coverage of Medicaid benefits must be set in the Medicaid capitated contract with the Medicaid managed care plan, we anticipate that States may seek technical assistance outside of the timeline for MA organizations to submit their State Medicaid agency contracts that are required by § 422.107(a) through (c).

Comment: In addition, a commenter suggested CMS clarify what happens in certain States that impose caps on Medicaid LTSS eligibility resulting in enrollment limits and how this carve-out provision would be applied or affected in those cases. This commenter also urged CMS take into consideration that, when determining criteria for carve-outs in applicable integrated plans, even minor Medicaid carve-outs can greatly complicate the unified grievances and appeals process to which they are subject, causing more confusion for beneficiaries and providers as well. The commenter suggested that CMS educate States about these impacts as part of the process.

Response: We thank the commenter. FIDE SNPs and HIDE SNPs are required by this rule to provide the minimum required Medicaid benefits to the extent that Medicaid coverage is available to beneficiaries who are eligible to enroll in the FIDE SNP or HIDE SNP. So, if the Medicaid State plan excludes coverage altogether of certain benefits for certain beneficiaries (that is, there is no Medicaid coverage at all, as opposed to Medicaid coverage being carved out of a managed care program or contract), our regulatory provision will not withhold designation of the D–SNP as a FIDE SNP or HIDE SNP solely based on that. Thus, FIDE SNPs are required to provide Medicaid LTSS to all who meet the State eligibility criteria for LTSS (for example, nursing home level of care) but not to all FIDE SNP enrollees, some of whom might not be eligible for the Medicaid benefit at all. HIDE SNPs are required to provide Medicaid LTSS, and/or Medicaid behavioral health services. To the extent Medicaid LTSS is not available to an enrollee because there is an enrollment cap or waiting list (for example, such as those related to Medicaid home and community-based services waivers), then the enrollee has not met the State eligibility criteria and the D–SNP could still meet the requirements at proposed § 422.107(g) and (h) to be a HIDE or FIDE SNP. Regarding applicable integrated plans, only the services covered by the applicable integrated plans are subject to the unified appeals and grievances processes. However, all D–SNPs that receive an appeal for a carved-out Medicaid services have a responsibility to assist the enrollee in the appeals process for that service, per § 422.562(a)(5).

Comment: Several commenters expressed concern that carve-outs may lead to disjointed and uncoordinated care and that carve-outs do not enhance care coordination. Another commenter indicated that they believe the proposal at § 422.107(g) and (h) impinges on State autonomy and flexibility.

Response: We appreciate the commenters' concerns and we acknowledge the commenters' perspective on this issue. However, we believe that the requirements proposed at § 422.107(g) and (h) strike an appropriate balance between the current realities of State managed care policy, applicable statutory provisions, and our implementation of those statutory provisions toward the goal of raising the bar on integration, while permitting State flexibility.

Comment: A commenter expressed concerns regarding the carve-out examples provided by CMS. Specifically, the commenter questioned use of substance abuse treatment, rural health clinic (RHC) and FQHC services as examples of permissible carve-outs, and requested feedback on whether the examples provided were appropriate. The commenter opined that these services are not limited in scope and should not be included as permissible carve-outs. The commenter noted that, according to the Substance Abuse and Mental Health Administration, dually eligible beneficiaries have a significantly higher rate of behavioral health and substance use disorder conditions than the non-dually eligible population. The commenter noted that, for many dually eligible individuals, RHCs and FQHCs are their primary source of behavioral health and

substance use disorder treatment. Therefore, the commenter requested that CMS not include these services as permissible carve-outs.

Response: We appreciate the comment and agree that the services identified are important to dually eligible individuals and care coordination would be facilitated if these services were not carved out from FIDE SNP or HIDE SNP Medicaid benefits. However, to our knowledge, only one State carves out FQHC and RHCs from Medicaid benefits covered under the FIDE SNP's or HIDE SNP's MCO contract with the State Medicaid agency. That State, Minnesota, has carved out Medicaid FQHC and RHC services from the benefits delivered by FIDE SNPs and HIDE SNPs because of the complexity in adjudicating Medicaid payments for these provider types and services. The State has implemented a data exchange process between these providers and the State's FIDE SNPs and HIDE SNPs to facilitate care coordination. At least six States carve substance use disorder services out from the services delivered by HIDE SNPs and FIDE SNPs. We believe the frequency of such carve-outs may be indicative of the difficulty in subsuming these services under Medicaid managed care. We do not have any information indicating that Medicaid behavioral health services or LTSS delivered by FQHCs and RHCs or substance use disorder services do not constitute a small part of the total scope of such services provided to the majority of beneficiaries eligible to enroll in these D–SNPs. Thus, we are finalizing language at § 422.107(g) and (h) that will continue to allow such limited carve-outs of Medicaid LTSS and Medicaid behavioral health services from the services covered by FIDE SNPs and HIDE SNPs. We will continue to assess whether these specific carve-outs meet our criteria in light of the specific facts in a given situation. In addition, we may consider future rulemaking to revise the standard in § 422.107(g) and (h) if necessary.

Comment: A commenter agreed with CMS that personal care services should not be carved out but also suggested that there could be instances where FIDE SNPs and HIDE SNPs do carve out services, such as behavioral health and Medicaid LTSS, and integration could still be achieved. This commenter provided an example where county personnel from the In-Home Supportive Services Program, California's carved-out personal care program, participated in care planning meetings with the MMP.

Response: We appreciate the comment and an example of engagement between personal care services staff and the MMP under circumstances where personal care services are carved out. While we recognize there may be other similar examples, as we discussed at 87 FR 1867 through 1868, our current policy, which we proposed and are finalizing in the definitions of FIDE SNP and HIDE SNP in § 422.2 and in § 422.107(g) and (h), is that FIDE SNP or HIDE SNP designation is not available for D–SNPs where the Medicaid coverage has extensive carve-outs of Medicaid behavioral health and/or Medicaid LTSS benefits. While we encourage the use of additional means of coordinating services, we do not believe that to be the appropriate standard to use.

Comment: A commenter requested additional clarification on how CMS views Medicaid carve-outs, including how CMS would address circumstances where a State's configuration of services and coverage differs from CMS's proposed requirements at §§ 422.2 and 422.107(g) and (h) for FIDE SNP and HIDE SNP coverage of Medicaid LTSS and Medicaid behavioral health services, as is the case in California. This commenter sought clarification of CMS's expectation that the FIDE SNP and/or HIDE SNP cover community-based LTSS. Similarly, the commenter requests information on CMS's view of behavioral health carve-outs in California, where behavioral health services for individuals with serious mental illness are the responsibility of the county mental health plan.

Response: Our proposal at § 422.107(g) through (h) does not change States' abilities to make decisions about its Medicaid managed care program or how services are delivered in Medicaid. Instead, our regulations at § 422.107(g) and (h) as well as the revisions to the definitions of FIDE SNP and HIDE SNP in § 422.2 limit the HIDE SNP and FIDE SNP designation based on the extent of carve-outs or exclusions from Medicaid coverage furnished under the Medicaid capitated contract required with the D–SNP or an affiliated Medicaid managed care plan. The current combination of LTSS and behavioral health carve-outs in California precludes most D–SNPs operating in California from qualifying for HIDE SNP or FIDE SNP designation.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.107(g) through (h) without modification.

f. Service Area Overlap Between FIDE SNPs and HIDE SNPs and Companion Medicaid Plans

MA organizations can achieve greater integration when they maximally align their FIDE SNP and HIDE SNP service areas with the service areas of the affiliated Medicaid managed care plan (meaning the entities that offer capitated Medicaid benefits for the same enrollees under a capitated contract with the State). Service area alignment also better comports with the minimum Medicare-Medicaid integration standards established by section 50311(b) of the BBA of 2018, which amended section 1859 of the Act. We codified the required level of integration for D–SNPs in paragraph (4) of the definition of D–SNP at § 422.2 in the April 2019 final rule.

Currently, under § 422.2, a D–SNP can meet the requirements to be designated as a FIDE SNP or HIDE SNP even if the service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans) affiliated with their organization.[37] For FIDE SNP or HIDE SNP enrollees outside the companion Medicaid plan's service area, this lack of alignment does little to integrate Medicare and Medicaid benefits as the D–SNP enrollee does not have the option to join the companion Medicaid plan. We believe requiring service area alignment in the definitions of FIDE SNP and HIDE SNP would encourage MA organizations and States to create better experiences for beneficiaries and move toward greater integration, which would be consistent with the amendments to section 1859(f) of the Act made by section 50311(b) of the BBA of 2018.

Under our authority at section 1859(f)(8)(D) of the Act to require that all D–SNPs meet certain criteria for Medicare and Medicaid integration, we proposed to amend the FIDE SNP definition at § 422.2 by adding new paragraph (6) and the HIDE SNP definition at § 422.2 by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D–SNP for plan year 2025 and subsequent years. Requiring the service area of the D–SNP contract to completely overlap with the service area of the Medicaid capitated (that is, managed care) contract will facilitate all

[37] CMS has acknowledged this and encouraged MA organizations to align these service areas in guidance issued on January 17, 2020, regarding D–SNPs. See *https://www.cms.gov/files/document/cy2021dsnpsmedicaremedicaidintegrationrequirements.pdf.*

FIDE SNP and HIDE SNP enrollees having access to both Medicare and Medicaid benefits from a single parent organization.

Our proposal addressed an unintended loophole to the minimum D–SNP integration criteria we adopted as part of the definitions of FIDE SNP and HIDE SNP: Where a D–SNP can qualify as either a FIDE SNP or HIDE SNP by only having a small portion of its service area (and therefore, enrollment) in the same service area as the companion Medicaid plan. We do not believe that the existing definitions are consistent with the goals and purposes of increasing Medicare-Medicaid integration for D–SNPs as a whole or particularly for FIDE SNPs and HIDE SNPs, which are supposed to have more than a bare minimum level of integration.

We did not intend for the proposal to limit State options for how they contract with managed care plans for their Medicaid programs, but to require the FIDE and HIDE SNPs to limit their MA service areas to areas within the service areas for the companion Medicaid plan. We did not propose to limit the service area of the companion Medicaid plan to that of the D–SNP service area. Therefore, the companion Medicaid plan may have a larger service area than the D–SNP. States, in their contracting arrangements for Medicaid managed care programs, may wish to limit the service areas of the affiliated Medicaid managed care plans, but we recognize that States may have other policy objectives better met with larger service areas in their Medicaid managed care programs.

In plan year 2022, all FIDE SNPs met the service area requirement being proposed. Most, but not all, HIDE SNPs also met the proposed requirement. Of the 219 HIDE SNP plan benefit packages across 18 States,[38] only 15 HIDE SNPs in four States had service area gaps with their affiliated Medicaid managed care plans, leaving 106,075 enrollees in 194 counties with no corresponding Medicaid plan.[39] As noted in our proposed rule, an MA organization impacted by our proposal would have several pathways to comply with the change to the definition of HIDE SNP at § 422.2. The options include using the crosswalk exception currently at § 422.530(c)(4) (which we are redesignating as § 422.530(c)(4)(i) in section II.A.6.a. of this final rule) in conjunction with dividing an existing FIDE or HIDE SNP into two (or more) separate D–SNPs, with the service area of the FIDE or HIDE SNP being within the service area of the affiliated Medicaid managed care plan. We solicited comment on whether this proposal would likely result in additional, unintended disruption for current FIDE SNP and HIDE SNP enrollment. We direct readers to the proposed rule, at 87 FR 1869, for a more detailed description of our projected impacts on HIDE SNPs and options available for MA organizations impacted by this change.

We explained in the proposed rule how we were considering an alternative of establishing a minimum percentage of enrollment or service area overlap between the D–SNP affiliated Medicaid plan and having FIDE SNPs and HIDE SNPs attest to meeting the minimum overlap requirement. We were also considering an amendment to explicitly codify how the current requirements permit D–SNPs to be designated as a FIDE SNP or HIDE SNP even if their service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans). We did not propose either of these alternative approaches because we believed these alternatives would create greater operational complexity (in the case of establishing a minimum percentage overlap) and would fail to help us achieve our objectives of clarifying options for beneficiaries and creating better coordination of Medicare and Medicaid benefits for all enrollees of the FIDE SNP or HIDE SNP compared to current practice.

Comment: A number of commenters supported of the proposal to require FIDE SNPs and HIDE SNPs have capitated contracts with the State Medicaid agency covering the entire service area for the D–SNP. A commenter noted that existing unaligned service areas for HIDE SNPs resulted in confusion among enrollees, providers, and plan staff and limited opportunities for integrated notices and appeals. Some commenters believed that CMS's proposal would increase Medicare-Medicaid integration. Several commenters noted CMS's proposal would facilitate the ability to offer exclusively aligned enrollment for D–SNP and the affiliated Medicaid plan. A commenter believed most, if not all, beneficiaries enrolled in HIDE SNPs and FIDE SNPs should have access to companion Medicaid plans. Another commenter noted that dually eligible individuals should be in Medicare and Medicaid plans under one parent company. Some commenters stated that CMS's proposal would clarify the definitions of FIDE SNPs and HIDE SNPs, and prevent less integrated plans from claiming these designations.

Response: We thank commenters for their support of our proposal. We agree that this change to the FIDE SNP and HIDE SNP definitions at § 422.2, and therefore in the requirements for these types of D–SNPs, will improve Medicare-Medicaid integration for dually eligible beneficiaries.

Comment: A commenter supported this proposal at the plan benefit package (PBP) level, rather than the contract level, in States where Medicare Advantage contracts include non-FIDE and non-HIDE PBPs that are D–SNPs. Another commenter supported the proposal and encouraged CMS to extend this requirement to all D–SNPs that operate in the same area as a Medicaid managed care plan, unless the State requests an exception. The commenter believed that when a State has risk contracts with managed care plans to provide Medicaid coverage to the dually eligible population, D–SNPs should only be permitted to operate if they have one of these Medicaid managed care contracts. This commenter believed that allowing integrated D–SNPs to compete with non-integrated D–SNPs confuses beneficiaries and degrades the definition of a D–SNP.

Response: We appreciate the support from these commenters. We confirm that the service area requirement we proposed and are finalizing here applies to FIDE SNPs and HIDE SNPs at the PBP level. While we did not accept the recommendation to deny D–SNP MA contracts to plans that do not (themselves or through an affiliated entity) have a capitated contract for Medicaid benefits with the State Medicaid agency in States where such contracts exist, we do note that States can choose to execute State Medicaid agency contract only with those D–SNPs that also cover Medicaid benefits under Medicaid managed care contracts, through a direct contract with the State or through an affiliated Medicaid managed care plan. Our final policy

[38] CMS, SNP Comprehensive report, January 2022. Retrieved at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.*

[39] Internal analysis based on data from: CMS, Monthly Enrollment by Contract, January 2022. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract*; CMS, Monthly Enrollment by Contract/Plan/State/County, January 2022. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract-Plan-State-County*; CMS, D–SNP Integration Levels for CY 2022. Retrieved from: *https://www.cms.gov/files/document/smacdsnpintegrationstatusesdatacy2022.xlsx*; and service area information from State Medicaid agency websites.

provides flexibility for States to permit coordination-only D–SNPs.

Comment: Some commenters opposed the requirement to align the FIDE SNP or HIDE SNP service area with the affiliated Medicaid plan service area. A few commenters expressed concern that the requirement will create significant, unnecessary disruption to existing D–SNP enrollees. A commenter believed requiring a Medicaid contract to cover the entire HIDE SNPs service area would limit the ability of small or new plans to offer a HIDE SNP and this would not be in beneficiaries' best interests.

Response: We appreciate the commenters' concern about the disruption to enrollees of FIDE SNPs and HIDE SNPs. We clarify that an impacted MA organization can keep operating in the existing service area for both the D–SNP and Medicaid plan; the difference would be that beginning with plan year 2025, the D–SNP would not qualify for FIDE SNP or HIDE SNP designation. Therefore, there is no need for a D–SNP to terminate and disrupt the coverage provided to current enrollees. The impacted MA organization that is not changing its service area or PBP offerings as a result of this rule would be required to update the contract with the State Medicaid agency required by § 422.107 to include the notification requirement specified at § 422.107(d). We note that, based on our review of D–SNP contracts for 2022, no FIDE SNPs are impacted by this requirement, and the States with impacted HIDE SNPs also offer non-HIDE D–SNPs; therefore, these States have established and are experienced with the notification requirement at § 422.107(d).

Comment: Several commenters also noted their concern about how the new service area requirement would negatively impact the State Medicaid agencies' contracting priorities and their ability to contract with D–SNPs. A few commenters requested CMS engage with impacted States to prevent any potential impacts and beneficiary disruption. A commenter requested further analysis and explanation of how the proposal would work with current State laws, and requested CMS research why there may be regions where a capitated contract does not extend to the entire D–SNP service area. Another commenter noted States may need some flexibility to come into compliance with the requirement and design programs and benefit offerings to meet their needs.

Response: We thank the commenters. However, we do not believe that this change will impact the flexibility that States have to use their contracts with D–SNPs to design programs that meet the needs of dually eligible beneficiaries. States can continue to contract with D–SNPs that have an affiliated Medicaid managed care plan in only a portion of the service area. While we agree with MACPAC's recommendation that States use the State Medicaid agency contracts that are required for D–SNPs by § 422.107(b) to completely align service areas between a D–SNP and a Medicaid managed care plan to better integrate coverage and care,[40] our proposal only mandates such alignment for HIDE SNP and FIDE SNPs with their affiliated Medicaid managed care plans. Coordination-only D–SNPs can continue to operate without alignment of the service area of the D–SNP with an affiliated Medicaid managed care plan. We continue to conduct outreach and technical assistance to States to better understand their use of capitated contracts (that is, Medicaid managed care contracts under 42 CFR part 438) and their Medicare-Medicaid integration goals.

Comment: A commenter noted that the proposed changes have already been implemented in Arizona. Another commenter expressed concern that the requirement would impact the landscape of D–SNPs in Oregon.

Response: We thank the commenters for offering their perspective. In our analysis of FIDE SNP and HIDE SNP service areas,[41] we identified some service areas in which HIDE SNPs in Arizona do not offer an affiliated Medicaid plan; however, we believe the impacted plans and the State have sufficient time to choose an approach to come into compliance (or default to coordination-only D–SNP status) that is in line with the State's integration goals. Our analysis also showed that HIDE SNPs in Oregon would not be impacted by this proposal because each of Oregon's HIDE SNPs' service areas completely overlap with an affiliated Medicaid plan. We will reach out to States impacted by this change to provide technical assistance in advance of the contract year 2025 MA bidding cycle.

Comment: A few commenters requested that CMS clarify the scope of the proposed requirement. A commenter requested clarification on whether this provision, or others in the rule, would limit HIDE SNP enrollments to exclusively aligned enrollment or otherwise limit HIDE SNPs with unaligned enrollment. Another commenter requested confirmation that an MA organization that has a Medicaid MCO contract that covers the applicable geography and that includes behavioral health benefits for dually eligible beneficiaries would be allowed to operate HIDE SNPs, even if the MA organization does not have a managed long-term services and supports (MLTSS) contract. The commenter also requested CMS confirm that an MA organization that offers a HIDE SNP that includes Medicaid services (including behavioral health) in the State Medicaid agency contract should not need to also have separate Medicaid MCO contract. Lastly, the commenter requested CMS clarify that an MA organization is not required to also have a general Medicaid MCO contract or MLTSS contract to offer a HIDE SNP if the State has separate selection process for integrated plans.

Response: We thank the commenters for their request for clarity on the scope of the proposals. We confirm that this provision and others being finalized in this rule do not require HIDE SNPs to have exclusively aligned enrollment. (The definitional change to require exclusively aligned enrollment beginning in 2025 is limited to FIDE SNPs.) We also note that in addition to requiring that the capitated contract with the State Medicaid agency cover the entire service area for the HIDE SNP starting in plan year 2025, the HIDE SNP definition as finalized in this rule requires: (1) The capitated contract be between the State Medicaid agency and the MA organization, it's parent organization, or another entity that is owned and controlled by its parent organization; (2) coverage of LTSS or behavioral health services. HIDE SNPs are not required to have a capitated contract with the State for both behavioral health and LTSS. These capitated contracts with the State Medicaid agency are Medicaid managed care risk contracts between the State and MA organization offering the HIDE SNP, its parent organization, or another entity owned and controlled by the

[40] MACPAC, Report to Congress on Medicaid and CHIP, ''Chapter 6: Improving Integration for Dually Eligible Beneficiaries: Strategies for State Contracts with Dual Eligible Special Needs Plan,'' June 2021. Retreived at *https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

[41] Internal analysis based on data from: CMS, Monthly Enrollment by Contract, March 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract*; CMS, Monthly Enrollment by Contract/Plan/State/County, March 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract-Plan-State-County*; CMS, D–SNP Integration Levels for CY 2021. Retrieved from: *https://www.cms.gov/files/document/smacdsnpintegrationstatusesdata.xlsx*; and service area information from State Medicaid agency websites.

parent organization and the Medicaid managed care risk contracts must comply with 42 CFR part 438 provisions for Medicaid managed care contracts. Therefore, the Medicaid managed care plan that is affiliated with a HIDE SNP may be an MCO, a PIHP, or a PAHP, so long as coverage of at least Medicaid LTSS or Medicaid behavioral health services is included. Under this additional amendment, the D–SNP's service area must be completely overlapped by the service area of this affiliated Medicaid managed care plan beginning in 2025 in order for the D–SNP to be a HIDE SNP; actual enrollment in the HIDE SNP and the affiliated Medicaid managed care plan is not required to be aligned. We note that some States directly contract with D–SNPs under a single contract that meets both the managed care contract requirements under 42 CFR part 438 and the D–SNP contract requirements under § 422.107, but this is not required and a State may use a Medicaid managed care contract under part 438 and a separate contract for § 422.107 purposes.

Comment: A few commenters supported CMS giving impacted MA organizations the opportunity to crosswalk enrollees from the existing D–SNP that includes the service area outside of the companion Medicaid plan service area into a new D–SNP PBP. However, several commenters noted creating two different PBPs creates additional burdens for MA organizations. A commenter also noted there is additional burden for the States to operate and oversee additional D–SNP PBPs.

Response: We thank the commenters for this feedback and recognize that creating a new PBP (that is, a new MA plan) creates additional burden for MA organizations. We reiterate that MA organizations do not need to change how they operate an impacted HIDE SNP. The HIDE SNP would lose its HIDE SNP designation and become a coordination-only D–SNP, which requires compliance with § 422.107(d). However, the D–SNP's contract with the State Medicaid agency under § 422.107(a) through (c) would likely need to be amended to include the notification requirement at § 422.107(d). We believe any burden to the State from an additional D–SNP PBP due to the notification requirement at § 422.107(d) or other State oversight of D–SNPs would be minimal. As noted previously in this section, all States with D–SNPs impacted by this provision already have coordination-only D–SNPs in their markets.

Comment: Some commenters suggested that CMS delay the proposed 2025 effective date of the requirement for service area overlap. While these commenters did not suggest an alternative effective date for this provision, they stated that it may take States and current HIDE SNPs longer to comply given State legislative and budgetary cycles.

Response: We recognize the commenters' concerns and acknowledge the difficulty with aligning State Medicaid agency and Medicare Advantage contracting timelines. However, we decline to make this change. For the HIDE SNPs that are not able to align their MA service area with the affiliated Medicaid plan's service area for contract year 2025, they may be able to continue operating as a non-HIDE D–SNP and regain HIDE status once the service areas align. We note, however, that this final rule is effective in 2022, more than two years before the beginning of 2025 when this new service area requirement will apply.

Comment: Several commenters requested CMS provide guidance to impacted States and MA organizations. A few commenters requested CMS educate States on how service area alignment impacts integrated care, and provide resources to help States address challenges such as different Medicaid procurement and D–SNP contract timelines. A commenter noted SHIP and MA brokers would also benefit from educational resources. Another commenter suggested that CMS educate beneficiaries ahead of this change.

Response: We thank the commenters for their input. We will continue to engage with States to understand challenges and priorities in establishing Medicare-Medicaid integration to improve beneficiary experience and integration options. We will provide education and outreach to States about changes in this final rule through the Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*). We are also exploring ways to improve awareness of available integrated care options for dually eligible beneficiaries.

Comment: A few commenters did not support the alternatives CMS considered to establish a minimum percentage of enrollment or service area overlap between the D–SNP and affiliated Medicaid plan. A commenter noted that these alternatives would cause confusion and limit opportunities for integration. A commenter supported the alternative of establishing a minimum percentage of enrollment at 75 percent or higher. This commenter noted that this percent would limit the number of FIDE SNP or HIDE SNP enrollees who find themselves without access to both Medicare and Medicaid benefits from a single parent organization but allow FIDE SNPs and HIDE SNPs in areas of the State where the companion Medicaid managed care plan may not be able to attract enough providers to meet network adequacy standards required by the State.

Response: We thank these commenters for their input. We acknowledge the difficulty for health plans to meet both Medicare and Medicaid network adequacy standards in rural areas. We are not finalizing the alternative considered of setting a minimum percentage of enrollment as we believe requiring FIDE SNPs and HIDE SNPs to have, beginning with the 2025 plan year, MA service areas that are entirely covered by the service area of the Medicaid capitated contact will create sufficiently better coordination of Medicare and Medicaid benefits compared to current practice.

Comment: Some commenters suggested that CMS allow existing HIDE SNPs to continue operating as HIDE SNPs and allow beneficiaries to choose to remain in unaligned plans. A commenter requested that CMS clarify network requirements to ensure alignment between a FIDE SNP's Medicare and Medicaid provider network. Another commenter suggested an attestation process which would require increasing levels of network alignment to maintain HIDE SNP status, similar to an initiative in Washington State.

Response: We thank commenters for their recommendations. We decline to accept the recommendation to allow existing HIDE SNPs to operate as HIDE SNPs despite not meeting this new requirement because this alternative may create greater operational complexity for overseeing HIDE SNPs and would fail to meet the objectives that underpinned our proposal.

Regarding network requirements to align the D–SNP's and companion Medicaid plan's provider networks, we will consider issuing future guidance and rulemaking on this topic. While we recognize the potential for improved continuity of care for dually eligible enrollees from State initiatives to increase the proportion of Medicaid plan providers in the D–SNP network alignment like the example from Washington State, this alternative is outside of the scope of this rulemaking.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendments at § 422.2 to the

FIDE SNP definition by adding new paragraph (6) and the HIDE SNP definition by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D–SNP for plan year 2025 and subsequent years.

6. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of MIPPA amended section 1859(f) of the Act to require that each D–SNP contract with the State Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. Implementing regulations are codified at § 422.107. Notwithstanding this State contracting requirement for D–SNPs, section 164(c)(4) of MIPPA does not obligate a State to contract with a D–SNP, which therefore provides States with significant control over the availability of D–SNPs in their markets. The State's discretion to contract with D–SNPs, combined with the State's control over its Medicaid program, creates flexibility for the State to require greater integration of Medicare and Medicaid benefits from the D–SNPs that operate in the State.

Even among States that have used the State Medicaid agency contract at § 422.107 to promote integration, we believe additional opportunities exist to improve beneficiary experiences and health plan oversight.

We proposed a new paragraph (e) at § 422.107 to describe conditions under which CMS would facilitate compliance with certain contract terms that States require of D–SNPs that operate in the State. As discussed in the proposed rule at 87 FR 1870, CMS would take certain steps when a State Medicaid agency's contracts with D–SNPs require exclusively aligned enrollment and require the D–SNPs to request (from CMS) MA contracts that only include one or more State-specific D–SNPs and that such D–SNPs use integrated member materials. As discussed below and in the proposed rule beginning at 87 FR 1870, the requirements described in proposed paragraph (e)(1) require work on the part of CMS to facilitate compliance by D–SNPs with the State's requirements. Therefore, proposed paragraphs (e)(2) and (3) described steps CMS would take when the conditions of proposed paragraph (e)(1) were met.

a. Limiting Certain MA Contracts to D–SNPs

Special needs plans, including D–SNPs, are currently included as separate MA plans, also known as ''plan benefit packages (PBPs),'' under the same contract number along with any other MA plans of the same product type (for example, health maintenance organization (HMO), preferred provider organization (PPO), etc.) offered by the legal entity that is the MA organization. As described in the proposed rule at 87 FR 1870, PBPs under a single contract may offer different benefit packages and serve multiple populations but still report medical loss ratios and certain quality measures at the contract level. While some quality measures are collected at the PBP level, unless a D–SNP is the only PBP in a contract, it is not possible to ascertain a full and complete picture of the quality performance of the D–SNP distinguished from other PBPs in the contract. In addition, there is currently no formal pathway for States to coordinate with CMS to require D–SNP PBPs to utilize model materials that integrate information regarding Medicare and Medicaid coverage.

It has been a long-standing CMS policy that CMS only award a legal entity one contract for each product type (for example, HMO, PPO, regional preferred provider organization (RPPO), etc.) it seeks to offer for all PBPs for the totality of the States, with limited exceptions.[42] Given the important distinctions of D–SNPs in comparison to other MA plans, States and other stakeholders have expressed an interest in better understanding performance of these plans without data being combined with non-D–SNPs and tailoring the information provided in member materials to more aptly suit the dually eligible population.

Therefore, we proposed to codify a pathway where if a State requires an MA organization to establish a MA contract that only includes one or more D–SNPs with exclusively aligned enrollment within a State and for that D–SNP to then utilize integrated materials, the MA organization may apply for such a contract using the existing MA application process. The proposed language at § 422.107(e)(1)(i) would give States the flexibility to require an MA organization to apply and seek CMS approval for one or more D–SNP-only contracts, which would provide more transparency in D–SNP plan performance within States. We direct readers to the proposed rule 87 FR 1870 for a more detailed explanation of the benefits and challenges of this proposal.

We described at proposed § 422.107(e)(2) how the CMS administrative steps to permit a new D–SNP-only contract would be initiated by receipt of a letter from the State Medicaid agency indicating its intention to include the contract requirements under § 422.107(e)(1) in its contract with specific MA organizations offering, or intending to offer, D–SNPs with exclusively aligned enrollment in the State. While we would provide States with additional information on timelines and procedures in sub-regulatory guidance, we would follow the steps consistent with existing timeframes and procedures for the submission of applications, bids, and other required materials to CMS. Examples of those activities are summarized in the proposed rule at 87 FR 1871. Our proposal did not include exemptions or changes in the current regulations and process for contract applications.

To avoid any significant beneficiary disruption while implementing the proposed change, we proposed a new crosswalk exception (to be codified at § 422.503(c)(4)(ii)) to allow MA organizations to seamlessly move existing D–SNP enrollees into a D–SNP-only contract created under this proposal. Our proposed crosswalk exception would apply only for movement between plans of the same product type (HMO, PPO, etc.) under the same parent organization for the following contract year when the new D–SNP is created under a new D–SNP-only contract based on a State requirement as described in proposed § 422.107(e). To add this new crosswalk exception, we proposed redesignating the existing paragraph (c)(4) as new paragraph (c)(4)(i) and creating a new paragraph (c)(4)(ii) in § 422.530. Under this proposal, the processes used for other crosswalk exceptions (for example, the notice to CMS and CMS's review and approval of the crosswalk exception) would apply to this new crosswalk exception.

We solicited comment on limiting certain MA contracts to D–SNPs and whether any additional beneficiary protections should apply.

Comment: Many commenters support this proposal as a step to improve quality, transparency, plan performance, and oversight of D–SNPs. Several commenters indicated having D–SNP-only contracts established under § 422.107(e) would enable a clearer understanding of the dually eligible population outcomes and needs in each

[42] The following memo outlines the policy for CY 2020, which has been in effect for several years: CMS HPMS Memo, ''Release of Notice of Intent to Apply for Contract Year 2021 Medicare Advantage (MA), Medicare-Medicaid Plans (MMP), and Prescription Drug Benefit (Part D) and Related CY 2021 Application Deadlines'', October 17, 2019. Retrieved from *https://www.cms.gov/files/document/2021-noia-partcpartd-mmp.pdf.*

State. MACPAC commented that the proposal aligned with prior work highlighting how States can use authority under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Pub. L. 110–275) to promote integration in their contracts with D–SNPs.

Response: We thank commenters for their support. We agree that having D–SNPs with exclusively aligned enrollment separated into distinct contracts will provide greater transparency into plan performance and ultimately improve quality for dually eligible enrollees.

Comment: Several commenters expressed support for efforts to encourage greater integration; however, they also expressed concerns with permitting States to request to CMS that D–SNPs with exclusively aligned enrollment be in separate MA contracts. Some commenters were concerned that the ability to have D–SNP-only contracts established under § 422.107(e) complicates State contracting requirements and could create barriers to new market entrants, thereby limiting enrollee choice and decreasing competition. A commenter encouraged CMS to ask States to implement the provisions of D–SNP-only contracts established under § 422.107(e) in a manner that does not discriminate between existing and new plans. Another commenter indicated that the proposal would create more heterogeneity among States in terms of State requirements for integrated plans and for quality assessments that will not improve evaluating or comparing plan quality for dually eligible individuals, indicating that D–SNPs already provide extensive quality information to States and CMS.

Response: We appreciate the commenters' perspectives on the potential impacts of having D–SNP-only contracts established under § 422.107(e); however, we do not believe that this proposal would cause States to discriminate between new and existing plans. Some States already limit market entry by only executing State Medicaid agency contracts with organizations with Medicaid MCO contracts or by utilizing competitive bidding and procurements to select organizations to participate as Medicaid MCOs. Our proposal does not change this existing State flexibility. As noted in the proposed rule at 87 FR 1869, section 164(c)(4) of MIPPA does not obligate a State to contract with a D–SNP, and therefore provides States with significant control over the availability of D–SNPs in their markets. States have flexibility in pursuing D–SNP-only contracts through § 422.107(e), but that flexibility is not unlimited. As we proposed and are finalizing, this pathway will only be available for D–SNPs that have exclusively aligned enrollment (which means that all the D–SNPs' enrollees are also enrolled in an affiliated Medicaid MCO) and where both a D–SNP-only contract and a minimum set of integrated materials are used. We believe in most circumstances it will be most beneficial if use of D–SNP-only MA contracts is implemented consistently for all D–SNPs with exclusively aligned enrollment within a State so that all these D–SNPs are on the same footing and these plan enrollees benefit from the use of integrated materials and greater transparency of quality ratings.

We disagree with the commenter that D–SNP-only contracts established under § 422.107(e) would not provide States with insight on D–SNP quality and performance. Unless a D–SNP is the only PBP in a contract, it is not possible to ascertain a complete picture of performance on HEDIS, CAHPS, HOS, and Star Ratings. As discussed below, the Star Ratings methodology includes both measure-level adjustments (where specified by measure stewards) and the CAI to adjust disparities in performance caused by social risk factors beyond the MA organizations' control.

Comment: A few commenters requested that CMS revisit the number of MA contracts a legal entity can hold or this proposal would limit the viability of some D–SNPs. Some commenters expressed concern that creating new legal entities is an expensive endeavor, including meeting State licensure and capital requirements. These commenters sought clarification if separate entities would be needed to enter into the D–SNP-only contracts established under § 422.107(e).

Response: We appreciate commenters' concerns regarding the number of MA contracts a legal entity can hold and agree that establishing new legal entities may be a burden to MA organizations. In the limited instance set forth in § 422.107(e), MA organizations with existing contracts that are required by the State to separate out the D–SNP with exclusively aligned enrollment would not be required to create a new legal entity and would be permitted the additional MA contract. CMS has authority, at § 422.503(e), to sever specific MA plans from a MA contract that covers multiple MA plans. While we have established an operational policy of requiring an MA contract to cover all MA plans of the same type for the same MA organization, we would create exceptions to that policy when § 422.107(e) applies.

Comment: Some commenters, as further discussed in section II.A.6.d., indicated that the proposal sets a framework that provides a clearer assessment of financial performance of D–SNPs.

Response: We thank the commenters for their input related to assessment of D–SNPs' financial performance. We agree that having D–SNP-only contracts established under § 422.107(e) will enhance States' and other stakeholder's ability to examine the financial performance of D–SNPs.

Comment: Some commenters noted D–SNP-only contracts established under § 422.107(e) would allow for better oversight of network adequacy for the dually eligible population.

Response: We thank commenters for their perspective related to oversight of network adequacy for the dually eligible population. We agree that having network submissions from D–SNP-only contracts established under § 422.107(e) will provide better oversight of network adequacy and insight on patterns of care unique to the dually eligible population in the covered service areas.

Comment: Some commenters supported the State flexibility in the proposal. A commenter indicated that the flexibility is necessary since States are at different points on the D–SNP integration pathway and noted that the requirements in the proposal would add duties for both State and D–SNP staff. A few commenters from one State indicated support for the proposal because current State policy would align with the ability to limit D–SNPs to D–SNP-only contracts specific to that State. A commenter acknowledged that they are actively considering implementing the option for D–SNP contracts established under § 422.107(e) should the proposal be finalized.

Response: We thank commenters for their support towards State flexibility. We anticipate that different States will implement this flexibility at different times as they progress along the pathway towards more integration of Medicaid and Medicare through their D–SNP contracts and engage with their contracted D–SNPs and CMS on this issue.

Comment: A commenter indicated that while the proposal could advance the goal for better alignment, care management, provider service and quality monitoring, many States will benefit from additional guidance and support to operationalize the proposal. Another commenter urged CMS to aid States in making these changes and proposed that CMS provide that support

through grants or enhanced Federal medical assistance percentage (FMAP) to address capacity issues. The commenter indicated that one-on-one intensive technical assistance and template materials would also be needed.

Response: We thank the commenters for their input. In addition to our own direct outreach to States, we will provide education and resources to States to support implementation of this rule through the Integrated Care Resource Center.[43] As discussed in the section that follows, we will develop template materials (see Integrated Member Materials).

We appreciate the commenter's request that CMS provide support through grants or enhanced FMAP to help States develop capacity to implement D–SNP-only contracts established under § 422.107(e). We will consider ways that CMS can provide support to States to further integration but note that there are limits on CMS's ability to issue grants or change FMAP levels.

Comment: A commenter expressed concern that timing of State decisions regarding D–SNP-only contracts established under § 422.107(e) will be unclear and inconsistent across markets, resulting in administrative challenges for plans.

Response: We agree with the commenter that the timing of State decisions regarding D–SNP-only contracts may not be consistent. To address this potential issue, we established at § 422.107(e)(2) that—because the timing of applications, bids, and other contracting procedures under §§ 422.250 through 422.530 remain applicable—CMS will work in good faith following receipt of a letter from a State Medicaid agency indicating their intent to pursue D–SNP-only contracts and the use of integrated materials to implement these provisions for a future contract year. We further direct the commenter's attention to the proposed timeline discussed in the proposed rule at 87 FR 1871. When we issue the additional information on timelines and procedures in sub-regulatory guidance, we will consider current MA timeframes and procedures for submission of applications, bids and other required materials to CMS, in addition to the need for MA organizations to make business decisions in a timely manner. We anticipate that efforts to achieve D–SNP-only MA contracts in a State may take two years or more, depending on current MA and Medicaid managed care contract arrangements, such as whether a current D–SNP has exclusively aligned enrollment, and the level of effort needed to develop integrated enrollee materials.

Comment: A commenter indicated support for the proposal only where the State and the plans agree to have D–SNP-only contracts established under § 422.107(e). Another commenter suggested limiting the option for D–SNP-only contracts established under § 422.107(e)(1) to those States where separate contracts are needed for additional State quality programs.

Response: We appreciate the commenter's support for establishing D–SNP-only contracts under § 422.107(e) where the State and the plans agree to take such steps. We recommend that the State consult with CMS, MA organizations, and other stakeholders on whether and how to pursue this step toward integration, but we recognize that section 164(c)(4) of MIPPA does not obligate a State to contract with a D–SNP, and therefore provides the States with significant control over which MA organizations offer D–SNPs in their markets. We disagree that the State requirements to establish D–SNP-only contracts under § 422.107(e) should be limited to circumstances where it is needed for additional State quality programs. While State quality programs may be facilitated by D–SNP-only contracts under § 422.107(e), there are other reasons, including transparency of MLRs and improved State oversight, that are also valid reasons for States to require such contracts.

Comment: A few commenters opposed the proposal indicating it may create additional administrative burden. A commenter cited burdens for the industry including transitioning enrollees to the new contract, providing separate Star Ratings measure support and reporting, managing additional HEDIS hybrid sample reviews and supplemental data work streams, and administering separate HOS and CAHPS surveys. In addition, the commenter noted that providers could be adversely impacted by additional HEDIS medical record reviews for hybrid measures and supplemental data collection efforts.

Response: We acknowledge the concerns raised by commenters that there may be additional administrative burden for MA organizations and providers. We anticipate that there will be impacts shared by CMS, States, and MA organizations as discussed in the proposed rule at 87 FR 1846 and in section V.C.3.b of this final rule; however, we believe the benefits from having separate D–SNP-only contracts established under § 422.107(e) outweigh these concerns. Further, we do not expect a large volume of new contracts would be created in the foreseeable future because most States do not meet the prerequisite of requiring exclusively aligned enrollment, and among those States that do, some D–SNPs are already in D–SNP-only contracts.

Comment: Many commenters expressed concerns regarding quality measurement for D–SNP-only contracts established under § 422.107(e). Citing anticipated smaller enrollment in D–SNP-only contracts established under § 422.107(e), many commenters believed CMS's proposal could create pervasive issues with small sample sizes, which may diminish reportability and reliability of various quality measures, thereby producing less visibility into D–SNP performance than with the current system. Some commenters were concerned that the variability in measure reporting would also affect the reliability of Star Ratings. Additionally, many commenters conveyed consternation based on their expectation that Star Ratings would be lower for D–SNP-only contracts established under § 422.107(e) because they would be scored against MA contracts with few or no dually eligible enrollees. A commenter noted that CMS research has shown a link between the length of time a contract has been in place and its Star Ratings performance. A few commenters noted that lower Star Ratings could reduce bonus payments and therefore rebates and supplemental benefits offered to beneficiaries. A commenter noted that lower bonus and rebate dollars may make it harder to address disparities. Finally, several commenters indicated that the impact to specific components of Star Ratings would need to be assessed further, including the Categorical Adjustment Index (CAI). A commenter noted that the CAI is insufficient to address concerns regarding lower Star Ratings for plans that disproportionately serve the most vulnerable populations. Additionally, a commenter expressed concern that moving to a separate contract would impact the Members Choosing to Leave the Plan measure, and asked CMS to exclude D–SNP enrollees switching between unaligned and aligned D–SNPs that are under the same parent organization.

Response: It is not clear to us that measure data from D–SNP-only contracts established under § 422.107(e) would be unreliable. Under the FAI demonstrations, MMPs have not experienced pervasive sample size issues, even with lower enrollment relative to broader MA contracts, and therefore we do not anticipate

[43] See *https://www.integratedcareresourcecenter.com/*.

widespread measurement issues for D–SNP-only contracts established under § 422.107(e). We also note that we would work with States interested in this opportunity to be sure they understand whether there is high risk of sample size problems and possible strategies for mitigation. That said, there are methodologies that prevent unreliable data from impacting Star Ratings. Star Ratings measures have minimum sample size and/or denominator requirements to ensure measure data are reliable. Further, to improve stability of cut points and prevent cut points from being influenced by outliers, Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings. Through the use of Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts.

We do not believe that a new D–SNP-only contract created under § 422.107(e) would likely have lower Star Ratings by virtue solely of being a new contract. The lower Star Ratings associated with new contracts is likely due to the time MA organizations need to implement quality improvement initiatives that impact Star Ratings. Such quality improvement initiatives should already be in place for MA contracts from which the new D–SNP-only contracts are carved out using the process under § 422.107(e). We anticipate that an MA organization would continue administrative and operational initiatives that are currently in place across multiple plans even if the D–SNP(s) in a particular State are placed into a D–SNP-only contract.

While we understand the concern that D–SNP-only contracts established under § 422.107(e) would be scored against MA contracts that may have few or no dually eligible enrollees, the Star Ratings methodology includes both measure-level adjustments where specified by measure stewards and the CAI to adjust for within-contract disparities in performance on social risk factors. There are currently 84 D–SNP-only contracts, and the CAI methodology works as intended in the presence of these contracts.[44] CAI values are assigned to contracts based on the contracts' percentage of LIS or dual eligible (DE) (LIS/DE) beneficiaries and the percentage of beneficiaries with disabilities. The percentage of LIS/DE beneficiaries is set to 100 percent for D–SNP-only contracts.

We are aware of the commenters' concern that the CAI does not fully address the challenge of achieving high Star Ratings for D–SNP-only contracts whose ratings are based on comparisons to MA contracts with few dually eligible enrollees. We continue to monitor the impact of the CAI, particularly to evaluate whether an increase in D–SNP-only contracts limits the statistical basis for the within-contract performance differences on which it is based, and whether any methodological enhancements are necessary. In addition, we refer commenters to the CY 2023 Advance Notice (*https://www.cms.gov/files/document/2023-advance-notice.pdf https://www.cms.gov/files/document/2023-advance-notice.pdf*) and CY 2023 Rate Announcement (*https://www.cms.gov/files/document/2023-announcement.pdf*) for information regarding a health equity index to potentially replace the current reward factor. The addition of a health equity index to the Star Ratings would need to be proposed through rulemaking.

Regarding the commenter's concern about the Members Choosing to Leave the Plan measure, we note that this measure currently excludes enrollees that are affected by a PBP termination. Therefore, we do not anticipate a negative impact to this measure when enrollees are crosswalked from the non-renewing D–SNP PBP into the new D–SNP-only contract established as described in § 422.107(e).

Comment: In lieu of creating D–SNP-only contracts established under § 422.107(e), many commenters suggested that the goals of this proposal could be met via other strategies. Many commenters recommended that CMS work with plans and States to either create D–SNP reporting and quality measures or expand the number of SNP-only measures reported at the PBP level. A commenter suggested that CMS require more detailed, stratified reporting of Star Ratings measures for D–SNPs. A commenter suggested that CMS consider additional reporting requirements in State Medicaid contracts, while a few commenters noted that States already have the option to require supplemental reporting for their Medicaid enrollees. A commenter noted the importance of ensuring that any State-specific quality measures are collected in a way that does not impose additional burden on D–SNPs.

Response: While we acknowledge that there are other strategies to collect quality data regarding D–SNPs other than permitting (or requiring) use of D–SNP-only contracts as described in § 422.107(e), the commenters' suggestions would not fully meet the goal of providing States and the public with greater transparency on MA quality ratings for D–SNPs. This can only be accomplished through separate Star Ratings specific to the performance of D–SNPs within a State. Although States may separately collect quality data for D–SNP enrollees, those data would not feed into Star Ratings. States also would not be able to collect CAHPS or HOS data specific to a D–SNP PBP, because the surveys are administered at the contract level. Furthermore, separate reporting reinforces unaligned measurement systems that exacerbate burden for plans and States, and may cause confusion for consumers as they attempt to consider quality information from different sources.

We note that in the CY 2023 Advance Notice and CY 2023 Rate Announcement, we discuss confidential stratified reporting of certain quality measures by dual eligible status, which will aid MA organizations in focusing quality improvement on dually eligible enrollees. Such reporting would not, however, feed into Star Ratings at this time.

Comment: A few commenters requested that CMS delay finalizing the proposal until a further evaluation can be done to determine all the consequences, while another commenter requested that CMS apply this provision prospectively for new D–SNP contracts awarded after the implementation date rather than requiring existing D–SNP PBPs to transition to separate D–SNP-only contracts. A commenter suggested that CMS not finalize the proposal at this time and instead monitor impacts of the changes occurring in California between 2023 and 2025.

Response: We acknowledge the commenters' interest in seeking a delay to implement this provision. Because of the timing of MA applications, bids, and contract execution, the earliest time that a separate D–SNP-only contract could be established using the process created by § 422.107(e) would be for the 2024 plan year, and then only if CMS receives a timely request from a State that is willing to meet the criteria set forth in § 422.107(e), the MA organization submits a timely notice of intent to apply and subsequent application for a D–SNP-only contract for a service area in the State, and the State and the MA organization successfully negotiate and execute the State Medicaid agency contract required by § 422.107(a) through (c). Therefore, we do not

[44] See 2022 SNP Landscape Source Files (v_10_26_21) retrieved at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn*.

believe a delay in the implementation of these provisions is necessary. Further, we believe that only implementing these provisions for new D–SNPs would constrain States that desire consistency in their contracting and oversight strategies and would preclude CMS, States, MA organizations, and other stakeholders from gaining a full understanding of plan performance to improve the quality of care and level of integration for the dually eligible population within a State.

Comment: Many commenters indicated that having D–SNP-only contracts established under § 422.107(e) would provide a complete picture of plan performance in areas like HEDIS, HOS, CAHPS, and Star Ratings. Several commenters encouraged transparency on the quality ratings for D–SNPs to better reflect experiences unique to the population. They noted that separate reporting will enable CMS, States, and plans to more fully analyze the data, thereby improving oversight and accountability. A commenter indicated that the proposal would provide more accurate benchmarks for plans serving dually eligible individuals. Another commenter noted that it may also provide insight into whether D–SNPs are measured on the right outcomes, and whether different or additional measures should be considered. Another commenter noted that this change could enable CMS to modify Star Rating criteria in the future to specifically account for the unique challenges of providing care for D–SNP beneficiaries.

Response: We thank commenters for their acknowledgement that our proposal would provide greater transparency on quality measurement for D–SNPs. We believe that separate reporting for D–SNP-only contracts has the potential to deliver many benefits, including enhancing oversight efforts and creating clearer performance expectations. We agree that separate reporting for D–SNP-only contracts will enable CMS to consider possible adjustments to the D–SNP measurement strategy in the future.

Comment: A commenter noted that this proposal would allow potential enrollees to compare Star Ratings more accurately across D–SNPs, since it would remove the impact of healthier MA membership on the Star Ratings for D–SNPs that are operated by plans with significant non-SNP MA membership. Another commenter noted that this proposal would allow agents and brokers to provide beneficiaries with more accurate plan metrics and enable better consumer decision-making.

Response: We agree with the commenters that separate Star Ratings for D–SNP-only contracts will provide valuable insights for consumers and the professionals who advise them. We believe that Star Ratings that are specific to local D–SNP(s) would be an important tool for comparison shopping and enhancing consumer choice.

Comment: Some commenters expressed concern for unintended consequences of assessing D–SNP-only contracts established under § 422.107(e) separately under the current Star Ratings methodology, and urged CMS to undergo a thorough evaluation and analysis on the impact of this proposal on Star Ratings. A few commenters asked CMS to consider developing modifications that account for differences with MA plans, while another commenter asked CMS to account for differences in population rather than quality of care provided by plans. A commenter wondered if further consideration should be given to comparing D–SNP performance exclusively to other D–SNPs when assessing Star Ratings, while another commenter contended that separate baselines and cut points may need to be created for the D–SNP-only contracts established under § 422.107(e). A few commenters referenced discussion in the CY 2023 Advance Notice about potential improvements to quality measurement to address social risk factors, and encouraged CMS to complete that effort before trying to measure D–SNP-only contracts established under § 422.107(e). A commenter urged CMS to work with plans to identify a long-term and more comprehensive solution to the impact of beneficiary demographics and social risk factors on Star Ratings. Another commenter suggested that CMS convene a technical expert panel to look at options for adjusting Star Ratings for D–SNPs. Finally, a commenter suggested that CMS evaluate D–SNPs with a different quality payment structure entirely, similar to the strategy used for MMPs.

Response: We are aware that for certain Star Ratings measures, it is challenging for most plans to achieve the same outcomes for groups with higher rates of disability, functional impairment, or social risk factors. This may be due to transportation issues, lower health literacy, communication challenges, residential instability, and other factors. As noted previously, the Star Ratings methodology includes both measure-level adjustments where specified by measure stewards and the CAI to adjust for within-contract disparities in performance on social risk factors. The CAI is a data-driven approach designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts. Many D–SNP contracts do well in the Star Ratings with 44 percent of D–SNP-only contracts earning 4 or more stars for the 2021 Star Ratings.

CMS continually seeks to refine the Star Ratings approach, and we encourage commenters to review the CY 2023 Advance Notice and CY 2023 Rate Announcement for information regarding potential new methodological enhancements related to expanding stratified reporting and developing a health equity index, both of which may help support efforts to address disparities in care and advance health equity. Substantive changes to the Star Ratings are adopted through the rulemaking process, which provides an opportunity for public notice and comment before CMS finalizes policy changes for the Star Ratings program.

Regarding the suggestion to create a different quality payment structure entirely for D–SNP-only contracts, MA payment requirements are set under statute, specifically section 1853 of the Act. We believe that Star Ratings are an effective motivator for performance that incentivize MA and Part D plans to provide quality care for all enrollees, including those that are socially at-risk. Furthermore, using the same ratings approach for all contracts helps consumers understand and compare quality across plan offerings.

Comment: A commenter expressed support that D–SNP-only contracts established under § 422.107(e) provide a pathway to D–SNP specific measurement. However, the commenter noted that combining D–SNP-only contracts established under § 422.107(e) with the transition of MMPs to D–SNPs would shift which populations are combined in a single Medicare contract with aggregated Star Ratings. The commenter recommended maintaining the ability to manage and see reporting at the product level for each of these distinct offerings to allow States to effectively measure and manage both programs.

Response: We appreciate the commenter's support that D–SNP-only contracts established under § 422.107(e) provide a pathway to D–SNP specific measurement. Our proposal does not preclude a State from requiring separate D–SNP-only contracts under § 422.107(e) for separate D–SNP programs serving distinct populations (for example, separate integrated care programs for dually eligible enrollees over and under age 65). In discussions

with States considering requiring such separate contracts, we would raise the issue with the applicable State(s) whether those contracts had sufficient enrollment for the calculation of Star Ratings.

Comment: Some commenters indicated that if CMS moves forward with this proposal, it should remove past performance as a factor in issuing the D–SNP-only contracts established under § 422.107(e). A commenter noted that low Star Ratings could prevent an organization from getting a D–SNP-only contract established under § 422.107(e) if CMS finalizes the proposal to include Star Ratings in past performance.

Response: We agree with commenters that MA organizations entering into a D–SNP-only contract based on the provisions set forth at § 422.107(e) should not be included in the past performance analysis as described in §§ 422.502 and 422.504. MA organizations that currently offer D–SNPs with exclusively aligned enrollment would not otherwise be seeking to enter into a D–SNP-only contract. We note that since the existing regulations at § 422.502(b)(1) provide CMS the flexibility of when to deny an application related to past performance that no changes are needed.

Comment: Several commenters, including MACPAC, suggested that CMS expand the ability of States to request that CMS allow D–SNP-only contracts established under § 422.107(e) beyond those D–SNPs with exclusively aligned enrollment. MACPAC and other commenters noted that a State's ability to assess quality in D–SNPs is important regardless of whether the D–SNP operates with exclusively aligned enrollment. A few commenters indicated that in order to ensure disparities between dual eligible enrollees are assessed on a level playing field, all D–SNPs should be in separate contracts from non-D–SNP MA plans. A commenter requested that CMS use the process as a template for a wider required, not optional, separation of D–SNP contracts in the future.

Response: We thank commenters for sharing their concerns on the parameters of this proposal to only apply to D–SNPs with exclusively aligned enrollment; however, we believe starting at this point is an incremental step on the integration platform. We will consider future rulemaking on whether to expand the ability for States to request to CMS separate D–SNP contracts for D–SNPs that do not have exclusively aligned enrollment.

Comment: A few commenters urged CMS to do more to allow for precise understanding of the policies, qualities, and obligations of specific D–SNPs by requiring separate contracts and public posting of model State Medicaid agency contracts. The commenters believe that this would improve oversight and allow data to more clearly reflect the outcomes, needs, satisfaction, and quality of care for people in D–SNPs.

Response: We appreciate the commenters' request that CMS require separate D–SNP-only contracts and public posting of model State Medicaid agency contracts in order to increase transparency about D–SNP obligations. We point the commenters to the Integrated Care Resource Center for sample language that State Medicaid agencies can use in their contracts.[45] As noted in response to other comments, we may also consider opportunities to expand or modify the approach for D–SNP-only contracts through future rulemaking.

Comment: A few commenters provided feedback regarding the ability of the MA organization offering a D–SNP under this proposal to crosswalk enrollees to the new D–SNP-only contract established under § 422.107(e). Some commenters expressed support for the new crosswalk proposed at § 422.530(c)(4)(ii) as it provides a smooth process for organizations to retain their enrollees. Some commenters expressed concern that moving the impacted enrollees to the new D–SNP-only contract would require a new enrollee identification card and could change bill routing by providers. Another commenter indicated that it would be important for plans to demonstrate how they will communicate the shift to beneficiaries in plain language and where to go for options counseling.

Response: We agree that these enrollees will need to receive a new identification card with the correct information. Our goal is to minimize enrollee disruption as we work towards more integrated care for the dually eligible population. We will work with States and the D–SNPs with exclusively aligned enrollment to appropriately communicate to the impacted enrollees why they are receiving new identification cards.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.107(e) regarding the creation of D–SNP-only contracts without modification, and we are finalizing our provisions at § 422.530(c)(4) with minor edits for clarification.

b. Integrated Member Materials

Communicating information to enrollees and potential enrollees is an important function of MA plans, Part D plans, and Medicaid managed care plans—and D–SNPs with exclusively aligned enrollment must comply with all of those rules.[46] There are advantages for enrollees in D–SNPs with exclusively aligned enrollment in receiving one set of communications that integrates all of the required content, as discussed later in this section. We proposed a mechanism and some parameters to facilitate a State's election to have D–SNPs with exclusively aligned enrollment use certain communications materials that integrate content about Medicare and Medicaid. As proposed and finalized, a State is only able to elect this if the State has also required the D–SNP with exclusively aligned enrollment to also apply for and seek CMS approval for a D–SNP-only MA contract. Under this rule, the applicable Medicaid managed care and MA requirements and standards continue to apply to the integrated materials.

CMS requires MA plans and Part D plans to furnish specific information to enrollees and potential enrollees, with some specific requirements outlined in §§ 422.111 and 423.128 and additional requirements at §§ 422.2261, 422.2267, 423.2261, and 423.2267. For information that CMS deems vital to Medicare beneficiaries, including information related to enrollment, benefits, health, and rights, CMS may develop and provide materials or content for MA organizations and Part D sponsors in either standardized or model form. These materials are subject to requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) and the Office of Management and Budget (OMB) collection of information approval process no less than every three years.[47] CMS creates *standardized* materials and content that MA organizations and Part D sponsors must use in the form and manner CMS provides under a separate OMB collection of information approval process. CMS *model* materials and

[45] See *https://www.integratedcareresourcecenter.com/resource/sample-language-state-medicaid-agency-contracts-dual-eligible-special-needs-plans.*

[46] Because D–SNPs must offer Part D benefits, they are subject to both MA requirements in part 422 and Part D requirements in part 423. *See* §§ 422.2 (definition of specialized MA plans for special needs individuals) and 422.500.

[47] Refer to *www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995* and *www.govinfo.gov/content/pkg/FR-1995-08-29/pdf/95-21235.pdf.*

content are examples of how to convey information to beneficiaries. MA organizations and Part D sponsors may use CMS's *model* materials or craft their own materials or content, provided the MA organization or Part D sponsor accurately conveys the vital and required information in the required material or content to the beneficiary and follows CMS's order of content, when specified. In §§ 422.2267 and 423.2267, we refer to such materials and content collectively as *required* materials.

CMS also includes similar, minimum Federal requirements in § 438.10 for Medicaid managed care plans (including MCOs) to furnish certain materials and information to enrollees and potential enrollees in a manner that is easily understood and readily accessible (OMB control number 0938–0920). Among the materials that Medicaid managed care plans must distribute are Enrollee Handbooks, Provider Directories, and Formularies.

As summarized in our proposed rule at 87 FR 1872 through 1873, the required materials that MA organizations and Part D sponsors must provide to current and prospective members and post to their websites by October 15 prior to the beginning of the plan year include the Evidence of Coverage (EOC) and the Annual Notice of Changes (ANOC), which are standardized communication materials. The required model communications materials include the Summary of Benefits (SB), Formulary, and Provider and Pharmacy Directories.

CMS encourages D–SNPs to add related Medicaid information in the EOC, ANOC, SB, and Provider Directory. Further integrating Medicare and Medicaid information in these required materials, as well as in the Formulary and Pharmacy Directory, would improve beneficiary experiences by providing a more seamless description of health care coverage and enhancing the understanding of, and satisfaction with, the coverage both programs provide.

In the proposed rule at 87 FR 1873, we described previous studies that assessed the effectiveness of integrated required materials for beneficiaries in the MMPs in the FAI and the Minnesota Senior Health Options (MSHO) plans in the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience. Beneficiaries provided positive feedback on the combined materials, as compared to separate Medicare and Medicaid materials. In addition, since 2019 CMS has worked with States and FIDE SNPs that are not demonstration participants to develop and annually update certain integrated materials that the States require and issue to plans.

For the States and FIDE SNPs we have worked with, we typically begin development of integrated national templates and State-specific models with the SB; a Formulary that contains Medicare Part D, Medicaid, and over the counter (OTC) drugs as well as non-drug OTC products; and one combined Medicare and Medicaid Provider and Pharmacy Directory. As described in our proposed rule, starting with these materials has several advantages, including that these materials integrate key Medicare and Medicaid information, they are required materials but are not standardized and, therefore, are not subject to the PRA clearance process, and the models are not lengthy or overly complex. They also offer opportunities for D–SNPs in different States with different Medicaid requirements to provide prospective and current dually eligible enrollees a more seamless presentation of essential information about their Medicare and Medicaid coverage. This would contribute to increased understanding of and satisfaction with the coverage both programs provide.

To provide a more coordinated beneficiary experience, we proposed at § 422.107(e) to codify a pathway by which, following receipt of a letter from a State Medicaid agency indicating their intent to pursue D–SNP-only contracts and the use of integrated model materials, CMS would coordinate with a State that chooses to require, through its State Medicaid agency contract, that a D–SNP with exclusively aligned enrollment use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. CMS will work with States to ensure these integrated materials comply with §§ 422.111, 422.2267(e)(11), 423.128, 423.2267(e), and 438.10(h). Proposed § 422.107(e)(1) established factual circumstances that would commit CMS to certain actions under proposed paragraphs (e)(2) and (3). We anticipate that there would be operational and administrative steps at the CMS and State level that would be necessary before a D–SNP could implement use of integrated communications materials, such as collaboration and coordination by CMS and the State on potential template materials, identification of potential conflicts between regulatory requirements at 42 CFR parts 422 and 423 for D–SNPs generally and 42 CFR part 438 and State law for the D–SNP's affiliated Medicaid MCO, and setting up a process for joint or coordinated review and oversight of the integrated materials. CMS annually reviews the contracts between States and D–SNPs that are required by § 422.107(b) each July for the following plan year. There would generally be insufficient time for the necessary operational and administrative steps to implement integrated communications materials between the review of the contract and the dates by which communications materials must be provided to current enrollees and made available for prospective enrollees during the annual coordinated election period that begins October 15 each year. Additionally, an MA organization would need to apply for a D–SNP-only contract consistent with existing timeframes for submission of applications, bids, and other required materials to CMS, and in accordance with forthcoming sub-regulatory guidance on timelines and procedures. Therefore, paragraph (e)(2) would require that CMS work in good faith with States upon receipt of a letter of intent regarding the State's inclusion of a requirement for a D–SNP with exclusively aligned enrollment to use integrated materials and apply for a D–SNP-only contract. We intended that these efforts include the work to develop model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D–SNP would use the integrated materials, and before D–SNP-only contracts are finalized.

We did not intend through this rule to significantly change timelines for plans to prepare materials nor did we intend to require any State to mandate that D–SNPs use integrated materials. We intended for this rule to assure interested States that CMS would do its part to make it possible for D–SNPs to comply with State Medicaid agency contract terms to use materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory if a State Medicaid agency seeks to require D–SNPs with exclusively aligned enrollment to perform as described at § 422.107(e)(1).

We considered including the EOC and ANOC as part of the minimum scope of integrated materials identified in § 422.107(e)(1)(ii). We explained in the proposed rule at 87 FR 1874 why we did not propose to include these alternative materials but solicited comment on whether these alternative materials should be included as part of the minimum scope of integration for D–SNPs. This rule would not preclude CMS and States from collaborating on

other integrated materials, including an integrated EOC or ANOC. As proposed, § 422.107(e) would apply only when a State required D–SNPs with exclusively aligned enrollment to use the minimum scope of integrated materials specified in paragraph (e)(1)(ii) and to seek CMS approval of D–SNP-only contracts. While we proposed minimum parameters, a State that wishes to require D–SNPs with exclusively aligned enrollment to do more (for example, use additional integrated materials) may do so using, or in conjunction with, the process in § 422.107(e). Further, we did not intend to prohibit or foreclose the possibility that CMS would work with States on other potential integration efforts that are not within the scope of § 422.107(e)(1).

Comment: Many commenters expressed support for the proposal to codify a pathway by which CMS would coordinate with a State that chooses to require, through its State Medicaid agency contract, that certain D–SNPs use an integrated Summary of Benefits (SB), Formulary, and combined Provider and Pharmacy Directory.

Numerous commenters stated that the proposed regulation would lead to reduced enrollee confusion because integrated materials would simplify and more clearly articulate the full scope of benefits across Medicare and Medicaid that are available through a given plan. A commenter noted that this proposed regulation would also simplify information for caregivers and advocates. Other commenters also stated that the proposed regulation would improve enrollee quality of and access to care and help enrollees understand how plan benefits can work together.

A commenter stated that integrated materials would create consistency for beneficiaries when evaluating plan choices. Another commenter noted that integrated materials would improve beneficiary awareness of integrated care options. A commenter also stated that integrated materials would help States and D–SNPs to provide clearer explanations of the advantages of integrated care, improve navigation of the health care system, and reduce health system fragmentation and administrative misalignment. Another commenter stated that the benefit of having Medicare and Medicaid plan information integrated into the same document is the reduction in mailings, a common request among enrollees.

Other commenters noted that States have successfully partnered with CMS to implement integrated materials. A commenter stated that the proposed regulation would create a pathway for States to continue to integrate materials.

Response: We appreciate the widespread support we received for our proposal to create a pathway for States to require certain D–SNPs with exclusively aligned enrollment and D–SNP-only contracts to use integrated materials. We concur that the integration of materials will increase understanding of available benefits, improve the enrollee experience, and decrease confusion by providing a simplified set of beneficiary materials.

Comment: A few commenters recommended that States be required to use their authority to standardize materials and ensure consistent messaging wherever possible. Other commenters noted their support of the flexibility in requiring the use of integrated materials, noting that States are at different points of integration, and that CMS's proposal would result in additional responsibilities for State and D–SNP staff.

Response: We acknowledge the interest in increasing the prevalence of integrated materials. However, we decline to require that States integrate materials, recognizing that States are at different phases of integration, and may have limited resources to devote to integrating materials. We concur that States should work to integrate materials when feasible and CMS will coordinate with them when possible.

Comment: A few commenters stated that CMS should provide States with clear direction and authority to ensure State-specific policies and requirements are included in integrated materials. A commenter continued to note that without such State-specific policy and requirements, integrated materials may not accurately reflect programmatic realities including important beneficiary-facing information such as cost-sharing responsibilities and eligibility rules.

Response: We acknowledge the commenters' concerns and, as we currently do with D–SNPs and Medicare-Medicaid Plans with integrated materials, we will work with States to ensure that, when a State requires a D–SNP to have integrated materials under § 422.107(e), the integrated materials accurately reflect applicable requirements for both Medicare Advantage and Medicaid managed care plans.

Comment: A few commenters recommended that States and CMS review materials in partnership, which is critical to develop comprehensive, accurate, and clear materials. Another commenter noted that States will need to provide information to D–SNPs and receive information from D–SNPs to ensure that information is kept up-to-date for materials such as integrated Provider Directories and information repositories for Medicaid.

Response: We thank the commenters for raising the importance of close collaboration and communication. We agree that coordination between CMS, States, and D–SNPs is necessary to ensure effective integration of model materials.

Comment: A commenter noted the operational challenges of integrating materials such as the different types of materials CMS and the State Medicaid agency require to be provided and differences in naming.

Response: We appreciate the comment and note that this rule focuses on materials which are required by both Medicare Advantage and Medicaid managed care regulations. We believe that integrating these materials will eliminate differences in naming and material formats and simplify the information for enrollees.

Comment: A few commenters noted that unaligned enrollment dates complicate efficient and timely distribution of integrated materials and suggested that CMS should work with States to implement necessary State and Federal changes that support alignment of enrollment dates. Another commenter urged CMS to limit its proposal to States where effective dates for Medicare and Medicaid plan years are aligned on the first day of the month. A commenter noted unaligned enrollment dates could cause members to receive duplicative information. The commenter also stated that there is no coordination between CMS and the State sending enrollment data to plans. They also noted that integrated materials can be operationally complex, as many plans automate the generation of enrollee materials on different platforms for Medicare and Medicaid plans.

Response: We appreciate the commenters' perspectives on this issue. We understand the potential for differences in enrollment dates between Medicare Advantage and Medicaid managed care plans and will continue to work with States to minimize enrollee disruption. In advance of implementation of integrated materials, CMS will discuss with participating States any differences in enrollment dates between Medicare Advantage and Medicaid managed care plans that may result from annual Medicare Advantage enrollment periods or State-specific enrollment timelines. Where differences in enrollment dates occur, CMS and the State will jointly decide on a strategy to implement integrated materials while

minimizing beneficiary confusion. Per § 422.107(e)(2), CMS will continue to work with a State so long as the State chooses to work with CMS on integrated materials. We believe that requiring integrated materials for enrollees with exclusively aligned enrollment in applicable States will help to reduce beneficiary confusion by providing one set of materials that combines Medicare and Medicaid information instead of two.

Comment: A commenter requested that CMS consider the challenges associated with Medicaid benefit and service carve-outs before implementing a requirement for D–SNPs to use integrated materials.

Response: We acknowledge the commenter's concern. We intend to work with States to ensure that the model materials include sufficient flexibility in order to adapt the description of benefits when needed.

Comment: A commenter stated that CMS should require States to indicate in their letters of intent that they have support from D–SNP partners to require integrated materials. The commenter believes CMS should require involvement and cooperation with participating D–SNPs in this process. The commenter suggested that CMS outline and require a standardized coordinated process across States for including or consulting with all plans in a given State with the goal of reaching consensus with all participating plans on basic models and changes.

Response: We thank the commenter for their input and suggestion. We intend to raise with States the importance of early and consistent collaboration with D–SNPs in advance of implementing any requirement for integrated materials. However, we believe the decision of whether to include this requirement in the State Medicaid agency contract should be left to the State.

Comment: A commenter stated that model documents for creating integrated materials have been invaluable, and especially helpful when models are developed for a particular State. These materials have State-specific references and data, which allows States to ensure enrollees across plans receive the same accurate State-specific information. Other commenters urged CMS to establish a consistent, standardized format for integrated materials that have been globally approved by States, instead of allowing each State to determine for itself.

Response: We appreciate the commenters perspectives on this issue. CMS will be creating models based off our experience on the FAI and a related demonstration in Minnesota for State use and will also collaborate with States to ensure that they appropriately integrate Medicare and Medicaid information for beneficiaries.

Comment: A commenter recommended that CMS should collaborate with States to develop a regulatory or other framework that aligns Medicaid managed care and D–SNP requirements into one clear set of governing rules for integrated materials.

Response: We thank the commenter for their suggestion and modified the regulation text at § 422.107(e)(1)(ii) to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of the chapter. As we work with States that take advantage of the new pathway created by § 422.107(e) and we gain additional experience in developing integrated materials with States, we may consider future rulemaking to establish integrated disclosure and communication materials where the applicable statutory authority permits sufficient flexibility.

Comment: Some commenters expressed concerns or were unsure of the timeframe for developing and implementing integrated materials. A commenter expressed concern that if a State is working on the State Medicaid agency contract during the same timeframe as it is developing integrated materials, the State may not have the ability to complete both tasks in a competent and thorough manner. A few commenters noted that CMS should take into consideration the timeframe of when States release their model materials, since State timeframes may differ from CMS timeframes. Another commenter recommended that the production schedule for integrated notices provide adequate time for use of focus groups to ensure that information is communicated effectively and meets the real needs of beneficiaries; the focus groups should consist of a diverse group of beneficiaries that is representative of each plan's demographic mix. A few commenters noted that they have experienced State backlogs in reviewing materials. A commenter requested that CMS work with the States to ensure State review is timely. Another commenter recommended that CMS require States to review plan materials within the existing HPMS platform and minimize template versions used at the State level. Other commenters believe States do not need to review all materials, noting that this can lead to backlogs in materials and place additional administrative burden on plans. MACPAC stated that States should have the opportunity to review all D–SNP integrated materials to ensure accuracy and improve beneficiary understanding of integration.

Response: We thank the commenters for sharing concerns about the timeline needed to implement integrated materials. We will work in good faith with participating States, following receipt of a letter from a State Medicaid agency indicating their intent to pursue D–SNP-only contracts and the use of integrated materials, to ensure that integrated models are provided to D–SNPs in a timely manner and intend to set clear timelines for review with the States. We note that that this proposal pertains only to those States that choose to require, through their State Medicaid agency contracts, that D–SNPs with exclusively aligned enrollment use integrated materials (and that these D–SNPs also apply for a D–SNP-only MA contract with CMS). We anticipate that there would be operational and administrative steps at CMS and each State that would be necessary before a D–SNP could implement integrated materials, such as collaboration and coordination by CMS and the State to identify potential conflicts between Federal regulatory requirements for D–SNPs and Medicaid managed care plans and State law and setting up a process for coordinated review and oversight of the integrated materials. Additionally, we modified the regulation text at § 422.107(e)(1)(ii) to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of the chapter; this change makes it clearer that § 422.107(e) does not create exceptions to other laws that govern the content and timing of materials provided to enrollees. Rather, our intent is to create a pathway for integrated materials to present all of the required information to enrollees in a more understandable and streamlined way.

CMS will work with the State to create model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D–SNP would use the integrated materials upon a receipt of a letter of intent regarding the State's inclusion of a requirement to use integrated materials and apply for a D–SNP-only contract. While these materials will be created based on models that have been tested as part of the FAI, we will ensure that the timeline accounts for any additional beneficiary testing, as necessary.

In order to allow sufficient time for the D–SNPs to populate required materials with plan-specific

information, submit applicable materials through HPMS, translate into any non-English language of at least five percent of the individuals in the service area, and make them available to beneficiaries by the required dates, we will aim to work with States to issue to the affected D–SNPs the required materials and instructions annually by the end of May for the following plan year. While we acknowledge that State review of only a subset of materials would save time and reduce administrative burden, we disagree with the suggestion to limit State review, because we believe that States should determine which integrated materials they want to review and then clarify this information with applicable D–SNPs.

Comment: A commenter recommended that CMS pilot this proposal with a small subset of plans and States before formalizing this proposal as an option for all States. They asked that CMS make this requirement effective no earlier than 2024.

Response: We thank the commenter for their suggestion and note that we have been piloting this approach with several States. Since 2019, we have worked with Massachusetts and New Jersey to develop and update certain integrated materials for FIDE SNPs in each State. For contract years 2020 and 2021, we provided high-level assistance to New York as the State developed select integrated materials that its exclusively aligned D–SNPs and Medicaid managed care plans, called Medicaid Advantage Plus plans, could use. We are also working with California to develop integrated materials for contract year 2023 for D–SNPs with exclusively aligned enrollment. We note that, based on the timeframes involved, the regulatory authority adopted in § 422.107(e) will apply to integrated materials that D–SNPs create for enrollment dates beginning with contract year 2024 if CMS receives a timely request from a State that is willing to meet the criteria set forth in § 422.107(e).

Comment: A few commenters requested more granular details and implementation guidance on this proposal.

Response: We appreciate the comments and anticipate that there will be operational and administrative steps at the CMS and State level before a D–SNP could implement integrated materials. D–SNPs required to use these integrated materials will receive additional information through State Medicaid agency contracts and model materials.

Comment: A number of commenters requested that CMS pay particular attention to linguistic and cultural competence and accessibility for people with disabilities. A commenter stated that greater effort is needed to ensure the information itself is more understandable to those at all levels of health literacy. They suggested that States test different messaging with dually eligible individuals, including individuals from diverse backgrounds and/or those with limited English proficiency, to create understandable materials with consistent messaging. They also noted that, to design messaging that resonates with dually eligible individuals, States should collaborate with community-based organizations and enrollment assisters. Some commenters stated that CMS should include a provision that accessibility, cultural competency, and translation requirements for integrated model materials should follow the standard (either State or Federal) which is more favorable to the beneficiary. A commenter recommended that CMS consider incorporating infographics, which may be easier for some enrollees to understand, into specific model documents. Another commenter noted that Provider Directories should be updated at least monthly and be available in multiple formats and languages, including American Sign Language. The commenter stated that beneficiaries should be able to access Provider Directories without submitting an account or policy number and should be able to distinguish between providers who are in network accepting new patients and providers who are not accepting new patients. They also noted that beneficiaries should be able to easily search Provider Directories by tier, product, languages spoken by provider in addition to languages available by interpreter, disability accessibility (accessible examination equipment, dressing room, parking etc.) and information about specialty and subspecialty providers.

Response: We appreciate the commenters' perspective on this issue and believe these are important goals. We did not propose and are not finalizing any waiver or exclusion from other, generally applicable, MA or Part D regulations concerning these mandatory disclosure documents from D–SNPs. In addition, as discussed in the proposed rule, the regulation at § 438.10 also addresses disclosure requirements for Medicaid managed care plans; we did not propose and are not finalizing exceptions to that regulation or other generally applicable rules for Medicaid managed care plans that apply to these mandatory disclosures either. In order to make that clear, we are finalizing a modification to the regulation text at § 422.107(e)(1)(ii) to require that the integrated model materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 423 of the chapter. Because D–SNPs must cover Part D benefits, they are subject to both the MA and Part D requirements when furnishing Provider and Pharmacy Directories. We note that §§ 422.2267(a)(2) and 423.2267(a)(2) require translation of required materials and content into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area. Similarly, § 438.10(d)(3) requires that Medicaid managed care contracts make available written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, in the prevalent non-English languages in a Medicaid managed care plan's particular service area. These requirements will continue to apply to a D–SNP with exclusively aligned enrollment and its affiliated Medicaid MCO when integrated materials are used as provided in § 422.107(e).

In § 422.112(a)(8), we require that MA organizations that offer MA coordinated care plans ensure that services are provided in a culturally competent manner to all enrollees, including to beneficiaries with limited English proficiency or reading skills, and diverse ethnic and cultural backgrounds. In addition, § 422.2267(e)(11)(iv) requires that MA organizations update Provider Directories any time the MA organization becomes aware of changes. Integrated materials must also meet requirements at § 438.10(h)(3), which requires Medicaid managed care plans to update an electronic provider directory no later than 30 calendar days after receiving updated provider information. We note that States can choose to include more stringent requirements for models in their State Medicaid agency contracts. We will take the additional recommendations regarding the Provider Directory into consideration when creating a model.

Comment: A commenter requested that CMS amend § 422.629 or § 422.630 or both to require D–SNPs to have specific publicly published procedures for making reasonable accommodation requests under the Americans with Disabilities Act, for D–SNP

consideration of such requests, and procedures for disputing denials of reasonable accommodation requests.

Response: While this comment is not strictly within the scope of this final rule, we note that MA plans, including D–SNPs, must comply with the applicable Federal civil rights authorities. Section 504 of the Rehabilitation Act of 1973 prohibits disability discrimination and includes requirements for effective communication for individuals with disabilities (45 CFR 84.52), accessibility standards for buildings and facilities (45 CFR 84.22 and 84.23), and the filing of grievances and complaints (45 CFR 84.61 and 84.7).

Comment: Some commenters requested that CMS extend this proposal beyond only those D–SNPs with exclusively aligned enrollment to those without D–SNP-only contracts or to all FIDE and HIDE SNPs. Other commenters suggested it apply to all D–SNPs. A commenter noted that having to implement separate material development and review processes can present operational challenges. A commenter requested that CMS define the ''certain D–SNPs'' in the proposal. A few commenters also requested that CMS clarify which materials require integration as well as which materials, or sections of materials, would require State feedback.

Response: We acknowledge that increased integration of materials for D–SNP enrollees and potential enrollees can help to reduce confusion and increase satisfaction. However, we proposed and are finalizing § 422.107(e) to adopt a pathway for States to require, through their State Medicaid agency contract, the use of integrated materials (at a minimum, an integrated SB, Formulary, and combined Provider and Pharmacy Directory) by D–SNPs with exclusively aligned enrollment, where the State is also requiring the D–SNP to apply for and request from CMS a D–SNP-only MA contract. By ''certain D–SNPs'' in the preamble of the proposed rule, we meant the D–SNPs that meet these specific requirements and are in this specific situation. Our proposal and final policy are limited to this group of D–SNPs because we believe exclusively aligned enrollment and a motivated State partner are both critical to effectively integrate materials. We will clarify through models and communication with States the sections of materials that require State feedback. We continue to work to improve current MA models for all D–SNPs, such as the ANOC and EOC, which allow D–SNPs to adjust the material to accurately reflect information such as Medicaid benefits and cost-sharing.

Comment: A number of commenters support the inclusion of the ANOC and the EOC as part of the minimum scope of integrated materials. Several commenters noted that they appreciate the ability to use the Member Handbook as the integrated model, noting that the Member Handbook is more enrollee-friendly than the EOC. A commenter stated that the ANOC provides critical information about the changes that beneficiaries need to consider during the Open Enrollment Period. They noted that the ANOC is relatively short and most likely to be read by the beneficiary. In addition, they stated that it helps to prevent surprises and disruptions because of unanticipated changes in coverage or providers. Another commenter noted that, since CMS cannot change timelines for preparation of materials, CMS should start with the SB, Formulary, and combined Provider and Pharmacy Directory and reassess integration of ANOCs and EOCs once these first documents are in place, except in cases where collaboration on those additional documents already exists. They request that as part of the reassessment of the ANOC and EOC documents in the PRA process, CMS should facilitate allowing D–SNPs to use the Member Handbook format and approach upon request and agreement with the State. If this is not possible, they request that CMS clarify what additional authorities are needed in order to do so.

Response: We appreciate the commenters' support for integrated ANOCs and EOCs. We have determined that we will take an incremental approach and finalize § 422.107(e)(1)(ii) as identifying the SB, Formulary, and combined Provider and Pharmacy Directory as the minimum set of documents to be integrated; these integrated materials must also meet Medicare and Medicaid managed care requirements in 42 CFR parts 422, 423, and 438. However, as stated in the proposed rule (87 FR 1874), we do not intend to preclude CMS and States from collaborating on other integrated materials, including an integrated ANOC or EOC.

We intend to develop an integrated Member Handbook (also known as the EOC) and ANOC for contract year 2024 through the PRA process, which will include making the documents available to the public for review and comment during the publication of 60- and 30-day **Federal Register** notices. These models will be based off of models that we created for the FAI and a related demonstration in Minnesota. We intend to make the integrated versions of these models available for States that want to collaborate with CMS in furthering the use of integrated materials by D–SNPs with exclusively aligned enrollment.

Comment: A commenter suggested that CMS consider establishing a CMS-centralized repository of State information that includes accurate State agency addresses, phone numbers, and State Pharmaceutical Assistance Program information that MA organizations can access and utilize for beneficiary communications such as ANOC and EOC. The commenter noted that this State information could be displayed in the same way CMS already provides Quality Improvement Organization information for each State.

Response: We thank the commenter for this suggestion and may re-examine it in the future. However, this comment is not within the scope of this rulemaking, as the proposed rule did not discuss a regulatory requirement for centralized State information.

Comment: The commenter suggested that an integrated ID card include information on the beneficiary's dual eligibility status, D–SNP type, the party that should receive and pay provider claims, and the party that is responsible for paying the beneficiary's cost-sharing obligations. The commenter stated that this will reduce administrative burden and reduce risk that a beneficiary is improperly billed.

Response: We thank the commenter for this suggestion. While setting new standards for the content of an integrated ID card is outside the scope of the regulation, we will consider including this information on ID cards in the future.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the provision at § 422.107(e)(ii) with a modification to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in 42 CFR parts 422, 423, and 438.

c. Joint State/CMS Oversight

MA organizations receiving capitated payments through MA and from the State Medicaid agency must comply with different sets of Medicare and Medicaid requirements. This includes requirements imposed at the State level that are not identical to Federal minimum standards for Medicaid managed care plans in 42 CFR part 438. We explained in the proposed rule, at 87 FR 1874, three drawbacks to CMS and States' separate infrastructures to

monitor compliance: (1) State regulators and CMS may be unaware of important compliance or performance problems related to the delivery of Medicare and Medicaid services; (2) State and CMS officials may pursue different performance improvement priorities; and (3) uncoordinated oversight by CMS and the States can create inefficiencies for health plans. We proposed to address these drawbacks by giving States the opportunity to collaborate with CMS on oversight activities for the specific D–SNPs that operate under the conditions described at proposed paragraph (e)(1). We received several comments supporting our overall approach to provide States an opportunity to collaborate with CMS on oversight activities.

Comment: Many commenters expressed support for State and CMS collaboration for joint oversight activities. Several commenters believed that improved data exchange and transparency would better align the State and CMS's improvement activities for D–SNPs. These commenters also noted that joint oversight would help the State and CMS establish awareness and appropriate accountability for plan performance. A few commenters noted that joint oversight is needed for quality of care and providing enrollees with a better integrated care experience. Several commenters indicated that increased collaboration would help the D–SNPs better manage staff resources in areas where there might be duplicative oversight activities. One commenter generally supports the opportunities for joint oversight and suggested guardrails to ensure that coordinated oversight activities are limited to D–SNPs to avoid overreach and promote improved outcomes and efficiencies.

Response: We thank the commenters for their support on our proposed rule. We agree that State and CMS collaboration for oversight activities of D–SNPs can increase transparency and improve efficiency of integrated care for Medicare and Medicaid services.

(1) State Access to the Health Plan Management System

The CMS Health Plan Management System (HPMS) is web-enabled information system where health and drug plans, plan consultants, third party vendors, and pharmaceutical manufacturers work with CMS to fulfill the plan enrollment, operational, and compliance requirements of the MA and Prescription Drug programs. We proposed in paragraph (e)(3)(i) that CMS would grant State access to HPMS to facilitate monitoring and oversight for D–SNPs operating under the specific contract terms required by the State that are described in proposed paragraph (e)(1).

The proposal would permit approved State Medicaid officials to use HPMS for a number of information sharing and oversight activities for these D–SNPs. This access would allow State users the ability to directly view D–SNP information without requiring the D–SNP to send the information separately.

We proposed that State access would be limited to approved users and subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances not described in our proposal. State access authorization would include access to information about the MA organization and the applicable D–SNP(s) and D–SNP-only contract, and information submitted by the MA organization through HPMS, under the specific circumstances described in the proposed regulation. We solicited feedback on our proposal, including feedback from MA organizations about CMS providing approved State officials with access to HPMS as a means to share information as it relates to the provisions of this final rule.

Comment: Many commenters expressed support for our proposal to grant State access to HPMS to facilitate monitoring and oversight of for D–SNPs operating under the specific contract terms required by the State that are described in § 422.107(e)(1). Some commenters noted that HPMS access is important for better information and oversight of D–SNPs. Other commenters noted that providing States with access to HPMS will give the State officials important insight into areas such as marketing materials, models of care, enrollee complaints, plan benefits, formulary, network, and other basic contract information without having to ask the D–SNP and as a result will streamline the oversight process. A commenter noted that granting certain State Medicaid agency officials access to HPMS, which CMS has identified as a useful practice, aligns with their recommendation that CMS apply best practices from the FAI to FIDE SNPs.

Response: We appreciate the commenters' support for providing State Medicaid officials with HPMS access. We agree that providing States with access to these areas of HPMS will improve the coordination and oversight of D–SNPs by States and CMS.

Comment: A commenter supported our proposal to grant States access to HPMS and suggested that CMS encourage States to update their State Medicaid agency contracts to reflect State access to this information. Specifically, the commenter encouraged States to eliminate the requirement that plans provide notices of audits since States will now be able to get the information through HPMS and will be able to have access to audit findings from CMS.

Response: We appreciate the commenter's perspective on this issue. We are not proposing to limit what States can include in their State Medicaid agency contracts, which are required by § 422.107(b) for all D–SNPs, but we hope that this new pathway for sharing information with States that require certain D–SNPs to use certain integrated materials and request a D–SNP-only MA contract with CMS will result in less burden for sharing information among the States that use this pathway, the affected D–SNPs, and CMS.

Comment: MACPAC and another commenter noted that limiting HPMS access to D–SNPs meeting the criteria of § 422.107(e) would mean that States would only be able to view information for a small number of D–SNPs with exclusively aligned enrollment and requested that CMS consider allowing States to view information for all D–SNPs. A commenter stated they understood there could be systems complexities with allowing States to access information for only a subset of enrollees when MA contracts include both D–SNP and non-D–SNP plan benefit packages. They suggest that CMS ensure that any language in the final rule is flexible enough to allow broader State access to HPMS without additional rulemaking. They believe that this was CMS's intent based on the language in the proposed rule stating: ''This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances . . .''

Response: CMS appreciates the commenters' support for providing State Medicaid officials with HPMS access. We will consider other options for permitting expanded HPMS access for State Medicaid officials over time. Under § 422.107(e), the regulation we proposed and are adopting here, access to States is tied to the D–SNP-only contracts for D–SNPs with exclusively aligned enrollment that are required to use specified integrated enrollee materials.

Comment: A commenter reiterated the importance of de-identifying information that could reveal the identity of the enrollee that has made a complaint, to ensure that their privacy

is upheld and to prevent any actions that could lead to or be perceived as enrollee retaliation. Another commenter requested CMS and State assurance of appropriate safeguards in place so that State employees accessing HPMS assure protection of proprietary information.

Response: CMS understands the commenters' concerns regarding enrollee privacy and the protection of proprietary information. Our experience granting States access to HPMS through the FAI and a related demonstration in Minnesota suggests that State access is without known problematic unintended consequences. In addition, we refer readers to our discussion in the proposed rule (87 FR 1874) that State users would be subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality.

Comment: A commenter proposed that enrollee complaint information be aggregated and stratified and that the information be utilized by health plans for quality improvement and performance purposes.

Response: We appreciate the comment. MA organizations have access to all of their enrollee complaints in HPMS and we encourage them to utilize the data for quality improvement purposes.

Comment: A commenter strongly recommend interoperability between State monitoring systems and HPMS.

Response: We appreciate the comment; however, it is outside the scope of this rulemaking.

After consideration of the comments received and for the reasons provided in the proposed rule and our responses to comments, we are finalizing § 422.107(e)(3)(i) as proposed to provide State Medicaid officials with access to HPMS for purposes of oversight of D–SNP contracts described in § 422.107(e)(1). We are also finalizing § 422.107(e)(1) and (2) as discussed elsewhere in this final rule.

(2) State-CMS Coordination on Program Audits

We proposed in paragraph (e)(3)(ii) that CMS would coordinate with State Medicaid officials on program audits. This coordination would include sharing major audit findings for State awareness related to the D–SNPs subject to proposed paragraph (e)(1).

As summarized in the proposed rule at 87 FR 1874 through 1875, we believe that there are benefits for CMS, States, and MA organizations to increasing coordination in connection with such audits. As proposed, CMS would also offer to work with States to attempt to avoid scheduling simultaneous State and Federal audits. This process would reduce the likelihood of concurrent Medicare and Medicaid program audits, thereby reducing the risk that an MA organization is insufficiently responsive to auditors or its performance slips because it is managing concurrent audits. While we described examples of how we may coordinate activities under the proposal, we did not intend to limit our discretion to coordinate with States in the audit process outside of the parameters in proposed § 422.107(e)(3)(ii); we would evaluate the extent of coordination in each circumstance relevant to the D–SNP-only contract established as a result of the State's contract requirements described in paragraph (e)(1).

Comment: Many commenters expressed support for the proposal for CMS-State coordination on program audits. Some commenters noted that greater State involvement provides States with valuable information and provides a stronger vantage point to determine plan performance. A few commenters indicated that program audits are resource intensive and plans face administrative burdens and challenges when State and Federal audits are concurrent. A commenter noted that when audits are concurrent this may decrease the plan's ability to respond appropriately and timely to audit inquires.

Response: CMS appreciates the commenters' support and agrees that there are benefits in increasing CMS, State, and MA organization coordination.

Comment: A few commenters recommended additional steps to coordinate audits across Medicare and Medicaid. A commenter suggested that CMS provide States with additional guidance on current Federal audits and NCQA model of care review requirements. The commenter believed that this type of coordination would allow regulators to consider if one audit could satisfy the requirements for both a Federal and State audit. The commenter also urged CMS to consider collaborating with States to develop a crosswalk for auditors and plans to reference to ensure all audit parameters are clear and not in conflict. Another commenter encouraged States to consider what audits have been performed by CMS and whenever possible the audits should be linked, deeming the D–SNPs that have clean audits as meeting standards. A commenter suggested that CMS improve coordination with States for other audit types and between audit divisions in CMS. This commenter indicated that it would be advantageous to have an increased level of scheduling coordination between Federal audit types; for example, between program audits and other routine reviews such as the one-third financial audit.

Response: CMS appreciates the perspectives and recommendations of the commenters for additional ways to coordinate audits and will take these into consideration for future audit-related work.

After consideration of the comments received and for the reasons provided in the proposed rule and our responses to comments, we are finalizing § 422.107(e)(3)(ii) as proposed address how CMS will coordinate with States on program audits for the D–SNP contracts described in § 422.107(e)(1).

(3) State Input on Provider Network Exceptions

As described in the proposed rule at 87 FR 1875, CMS expects to use existing authority and flexibility as it pertains to the review of MA plan provider networks, particularly in CMS's review of network exceptions, to solicit and receive input from State Medicaid agencies. CMS requires all MA organizations to maintain a network of appropriate providers that is sufficient to provide adequate access to covered services. Currently, MA organizations submit their provider networks to CMS for review at the overall contract level on a triennial basis or when there is a triggering event such as an application or a significant provider/facility termination.[48] As discussed in the proposed rule at 87 FR 1875, if an MA organization that offers one or more D–SNPs seeks an exception to our network adequacy standards in § 422.116, State Medicaid officials may be uniquely positioned to provide relevant information to CMS. We did not propose to adopt specific regulation text in § 422.107(e)(3) regarding potential collaboration with State Medicaid agencies in connection with adjudicating requests for an exception to network adequacy requirements for D–SNPs that operate under the conditions described at proposed paragraph (e)(1) because a regulatory amendment is not necessary to support this process; however, the proposed rule outlined how we expect this type of engagement between CMS and States to work.

When an MA plan fails to meet the network adequacy criteria in § 422.116(b) through (e), the MA plan

[48] Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (Last updated: June 17, 2020). Retrieved at Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (*cms.gov*).

may request an exception. Exceptions are limited to specific situations and conditions identified in § 422.116(f)(1) and, in considering whether to grant an exception, CMS considers whether current access to providers and facilities is different from what appears to be indicated by the data CMS uses to evaluate and set minimum standards for network adequacy for MA plans.

In the proposed rule, CMS proposed to amend § 422.116(a)(1)(ii) to require compliance with network adequacy standards as part of an application for a new or expanding MA service area (see section II.C. of this final rule). In addition, we described our intent to reach out to States to learn if there is any information that would meet the requirement at § 422.116(f)(2)(ii) when a MA organization with a D–SNP contract described in § 422.107(e) submits an exception request. CMS may consult with the respective State to identify if there are other factors, as described at § 422.112(a)(10), that may be relevant before making a determination on the exception request. We solicited comment on this approach.

Comment: We received a number of comments expressing support for our efforts to consult with States when an MA organization with a D–SNP contract described in § 422.107(e)(1) submits an exception request that does not meet the requirements at § 422.116(f)(1). A few commenters indicated that the States have information that would be pertinent to CMS's determinations. Some commenters noted that States have a deep knowledge of their local markets and can help CMS determine the validity of plans' exception requests. A commenter also suggested that States' involvement in the network exception process can highlight provider shortages.

Response: CMS appreciates the commenters' support for our efforts to consult with and solicit input from States in these circumstances.

Comment: A few commenters recommended that we add a provision that CMS notify the D–SNP of the consultation with the State so that the D–SNP is fully informed of additional factors being considered in the exception request.

Response: We appreciate the commenters' interest in having CMS notify a D–SNP when CMS consults with or solicits input from a State on a specific exception request. We decline to adopt a requirement that CMS notify the D–SNP whenever we consult with a State on an exception request because it would be too burdensome given the short timeframe we take to review all exception requests, in general. The D–SNP will ultimately be informed of the basis for CMS's approval or denial of the exception request, and we do not believe there is any added benefit to the D–SNP knowing about the State outreach during the exception review process.

Comment: A commenter requested that we consider the timeliness in receiving responses from the State(s).

Response: We thank the commenter for their request and note that we expect States to respond timely to our requests to engage with CMS and to provide us with information that will be relevant to our determinations on exception requests submitted by MA organizations with D–SNP contracts described in § 422.107(e). To the extent States are not willing or able to provide information in a timely fashion, we will proceed with the network adequacy determination with the information available to us.

Comment: We received a few comments that did not support the proposal for State input of Medicare network exception requests on the grounds that States already have network standards in place and may not have specific insights into the Medicare requirements.

Response: We believe the commenters misinterpreted the discussion of CMS's authority under § 422.116(f) and our intent to solicit and receive input from State Medicaid agencies. Our consultations with States in the context of our proposal are limited to exception requests to the MA network adequacy standards and do not involve State Medicaid network standards. The purpose of the consultation with the State is to help CMS gain access to information that may be relevant to our determinations on exception requests from MA organizations with D–SNP contracts described in § 422.107(e).

The discussion in the proposed rule on this topic was not a proposal, and we are not finalizing any rules or regulations about CMS's ability to solicit comment from and consult with a State regarding a request from certain MA organizations (specifically, MA organizations with a D–SNP-only MA contract described in § 422.107(e)) for an exception from the MA network adequacy requirements in § 422.116. As described in the proposed rule and our responses to comments, we intend to solicit comment from and engage with States as appropriate and necessary when evaluating requests for exceptions from the network adequacy requirements in § 422.116.

d. Comment Solicitation on Financing Issues

Based on our experience in the FAI, we solicited comments on two opportunities to advance financial integration for integrated plans: (1) Medicare medical loss ratios (MLRs) that include only D–SNP experience and other options to evaluate the financial performance of integrated plans; and (2) consideration of the expected impact of benefits provided by MA organizations on Medicaid cost and utilization in the evaluation of Medicaid actuarial soundness.

We did not propose new Medicare or Medicaid policies in this discussion. Instead, we requested public comments on possible future initiatives. In this section of this rule, we summarize our requests for comments, comments received, and provide our responses.

At 86 FR 1870, we proposed at § 422.107(e) to make an option available through which States could require D–SNPs with exclusively aligned enrollment to operate under MA contracts that only include one or more D–SNPs that operate in that State. Such D–SNPs would still have to calculate and report separate Medicare and Medicaid MLRs, and having a separate contract for certain D–SNPs would better allow evaluation of MLRs and financial performance specific to that D–SNP product. We solicited feedback on the extent to which the proposal at § 422.107(e) would better allow States to evaluate the performance of integrated plans.

In the discussion at 87 FR 1877, we noted that we believe that Medicaid managed care capitation rates can be actuarially sound as required by § 438.4 when those rates consider the impact of MA supplemental benefits and any State-specific requirements for dually eligible individuals on the projected costs and utilization of the Medicaid benefits covered by the Medicaid managed care capitation rates. We solicited feedback on the extent to which this consideration of the impact of Medicare-covered benefits on costs and utilization of Medicaid services advances integration goals and is consistent with actuarial standards of practice. We also requested input on what information States, actuaries, and others would need to evaluate actuarial soundness under this approach.

Finally, we solicited feedback on other options related to financing for integrated plans CMS should evaluate and consider for future rulemaking or sub-regulatory clarification.

Comment: Several commenters expressed support for approaches to

MLR reporting that meaningfully improve stakeholders' visibility into the financial performance of integrated plans. Some commenters agreed that the proposal at § 422.107(e) would provide for MLR results exclusive to D–SNPs with exclusively aligned enrollment, thus enhancing transparency and relevancy of the MLR data used to assess and oversee financial performance for these plans in a way not currently possible. A commenter noted stakeholders already collect and analyze Medicare and Medicaid financial data and the benefits of the proposal would depend on the extent to which CMS facilitated or standardized analysis of MLR data in ways not possible today. Finally, a commenter recommended CMS explore how MLR calculations can improve services and outcomes for dually eligible individuals, especially those enrolled in HIDE and FIDE SNPs.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future rulemaking and in developing technical assistance for States in analyzing MLR data.

Comment: Some commenters stated separate Medicaid and Medicare MLR requirements create challenges to meeting integration goals, such as inhibiting flexibility and not incentivizing integrated care, while another commenter stated the inconsistent availability of encounter data and lack of framework for allocating cost to Medicare versus Medicaid pose significant challenges.

A commenter objected to CMS ending the FAI capitated financial alignment model and expressed that this represents an undesirable move away from an integrated MLR, a change they believed would erode transparency in medical spending and increase the risk that plans will pad allowable administrative costs.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future rulemaking. We address other comments on the FAI later in this final rulemaking.

Comment: Many commenters supported maintaining separate Medicare and Medicaid MLR requirements and several commenters expressed opposition to any changes. A few commenters expressed uncertainty that the benefits of an integrated MLR would outweigh the burden of reporting integrated MLR data. A commenter opposed any requirement for D–SNPs to report an integrated MLR or any other changes to current D–SNP financing and infrastructure. Many commenters also noted barriers to or concerns with integrated MLR reporting that they believe CMS should take into consideration, including misalignments between Medicare and Medicaid funding, cost reporting definitions, and program requirements; the lack of a standardized methodology for calculating an integrated MLR; and the fact that current Medicaid rate development guidance does not provide for an integrated MLR to be used in Medicaid rate development for an integrated D–SNP. Some commenters indicated plans' operational and financial workflows are not currently structured to support or yield encounter or financial data of sufficient quality to support integrated MLR reporting.

A few commenters expressed support for integrated MLR reporting. A few commenters responded that they do not believe the current MLR approach provides sufficient data for State decision making and policy development; they instead supported an integrated MLR approach, including CMS requiring an integrated MLR for integrated products, as a better way to track and oversee plan spending, set actuarially sound rates, and establish plan performance targets. Several commenters supported States having the flexibility to determine MLR requirements. A commenter stated the integrated MLR reports that MMPs submit under FAI offer a more complete picture of plan financial performance than would otherwise be available. Another commenter acknowledged what while there are significant technical and legal hurdles to achieving integrated MLR reporting, overcoming these would support data-driven decision making and policy. A commenter noted the potential benefit to States of CMS's proposed requirement to reinstate the detailed MLR reporting requirements under §§ 422.2460 and 423.2460 (87 FR 1902 through 1906) as it may better support States to compare Medicare and Medicaid MLR reporting under a D–SNP contract.

Response: We would like to clarify that we did not propose to require an integrated MLR for integrated products; as we stated at 87 FR 1876, we do not believe we have the statutory authority to include Medicaid experience as part of the Medicare MLR requirement. We thank the commenters for providing thoughtful input on these issues. We will take these comments and concerns into consideration for any future guidance on this topic.

Comment: Several commenters agreed with CMS's interpretation that Medicaid managed care capitation rates can be actuarially sound, as required by § 438.4, when those rates consider the impact of MA supplemental benefits and State-specific requirements for dually eligible individuals, as included in the State Medicaid agency contract, D–SNP MOC, or MMP contract, on Medicaid costs and utilization. A few other commenters did not reference Medicaid actuarial soundness requirements but stated that MA supplemental benefits and State-specific requirements should be considered in setting Medicaid managed care capitation rates or supported States having the flexibility to consider the impact of such benefits and requirements when setting Medicaid managed care capitation rates. Several commenters indicated they expect MA supplemental benefits or other State-specific requirements to have minimal impact on the cost and utilization of Medicaid benefits. A commenter recommended that Medicaid actuaries be required to consider the impact of Medicare costs and utilization in Medicaid rate setting.

A few commenters expressed concern with States considering the impact of MA supplemental benefits and other State-specific requirements for dually eligible individuals when establishing Medicaid managed care capitation rates, citing potential negative impacts including: Reductions in Medicaid managed care capitation rates without sufficient transparency; Medicaid rates not meeting actuarial soundness requirements; and States offering less robust Medicaid benefits by substituting these benefits with MA supplemental benefits. A few commenters expressed concern about the impact of these Medicaid-rate setting considerations on MA market dynamics or beneficiaries' access to certain benefits, including: the potential for D–SNPs to be less competitive; or for such benefits to only be made available in MA plans, resulting in less beneficiary choice. For example, a commenter stated that significant expansion of MA supplemental benefits could give States less incentive to expand their Medicaid benefit package if coverage, such as for dental care, were widely provided in MA plans that are available to dually eligible individuals; in such scenario, beneficiary choice could be limited if needed dental coverage were only available in MA plans. A commenter also expressed concern that for integrated products, Medicare financial information alone might suggest funds are available to support funding Medicaid benefits, but that combined Medicare and Medicaid funding could indicate otherwise, limiting an

integrated plan's ability to fund investments in Medicaid services with savings from reduced Medicare acute care utilization. A few commenters stated that CMS should also consider the impact of Medicaid benefits in lowering Medicare costs and utilization.

Response: We thank the commenters for providing thoughtful input on this issue. We appreciate the support for CMS's interpretation that Medicaid managed care capitation rates can be actuarially sound when those rates consider the impact of MA supplemental benefits and any State-specific requirements on the projected costs and utilization of the Medicaid benefits. We thank the commenters for providing input on the potential unanticipated impacts of such an approach. We will take these comments and concerns into consideration for any future guidance on this topic.

Comment: A number of commenters provided input on the types of information States, actuaries, and others would need to evaluate actuarial soundness under this approach. A commenter noted that Medicaid rate development for programs with enrollment aligned across Medicare and Medicaid may currently use a wide variety of information that generally meets actuarial soundness needs. However, this commenter and a number of others provided feedback on potential implementation challenges CMS should consider that could impact States' and actuaries' ability to estimate the impact of such supplemental benefits on Medicaid costs and utilization. Commenters noted barriers including: Timing differences between the MA bidding cycle and Medicaid rate-setting periods; the lack of uniformity and sameness in supplemental benefits across MA plans or within MA plans as a result of MA uniformity flexibility or provision of SSBCI; States not having sufficient MA bid data that describes supplemental benefits, and the lack of a consistent framework for allocating Medicare versus Medicaid costs or claims.

Some commenters encouraged CMS to provide additional guidance to ensure consistency in how States and actuaries consider of the impact on MA supplemental benefits or State-specific requirements in Medicaid managed care rate setting, in areas including: CMS's expectations for plan-specific Medicaid rates to account for plan differences in MA supplemental benefits; using a historical MA benefits package to establish Medicaid rates; and what quantitative support would be necessary to support CMS' review of Medicaid rates in these scenarios.

Response: We appreciate the feedback on the additional information States, actuaries and others would need to evaluate actuarial soundness under this approach, as well as other potential implementation challenges. We also thank the commenters for their input concerning what guidance would be useful for States and Medicaid actuaries. We will take this input into account as we consider updates to CMS's Medicaid Managed Care Rate Development Guide, as well as other avenues to provide guidance and technical assistance on this topic.

Comment: We received many comments on other options related to financing for integrated plans. For any future rulemaking, a commenter requested CMS collaborate with stakeholders in advance, while another commenter requested CMS take into consideration plans' need for flexible deadlines and written guidance.

Many commenters recommended that CMS work with States, managed care organizations, and actuaries on opportunities to improve financial alignment between Medicare and Medicaid. Other commenters expressed interest in CMS sharing best practices, such as how experience from the FAI could be applied in the context of a D–SNP or a FIDE SNP, or continuing to explore topics related to financial alignment, such as curbing incentives for cost shifting, methodologies to value supplemental benefits, and investments that target social determinants of health. A commenter that believes CMS should increase the level of coordination between CMS and States regarding community supports and in-lieu-of services that impact Medicare costs and utilization requested a new requirement for advance notification of changes in community support services.

A few commenters emphasized their support for CMS examining experienced-based rate setting approaches for adoption in integrated products outside of FAI, where cost neutrality was required. A commenter noted States participating in other aligned approaches may want to consider requesting more explicit cost offsets from CMS, such as sharing in the Medicare MLR remittances. A few commenters encouraged CMS to continue to offer States financial incentives for integration, with a commenter suggesting CMS offer States alternative value-adds such as access to implementation resources; ongoing increased FFP for administrative and IT changes; and improved coordination, quality, access, and simplification for beneficiaries.

Finally, a few commenters disagreed with the degree of emphasis they believe is placed on financial savings derived from integrated products, arguing CMS should pursue integration because it is an alternative to the current fragmented, inefficient system. A commenter disagreed with designing integrated approaches under a standard of budget neutrality, noting this is a standard to which MA organizations and Medicaid capitation payments for D–SNPs are not likewise held. Another commenter expressed support for replacing Titles 18 and 19 of the SSA to fund integrated services through a single source of financing used to fund benefits; this commenter stated this alternative model should feature State contracting with administering entities, financing mechanisms to ensure accountability and eliminate incentives for cost shifting, and required reinvestments of savings into efforts to support the population.

Response: We appreciate the commenters' input and suggestions on how to improve financial alignment across the Medicare and Medicaid programs and will take them under advisement for future rulemaking.

7. Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

In § 422.561, we proposed to expand the universe of D–SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs in which Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D–SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D–SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We limited the universe of potential applicable integrated plans to FIDE SNPs and HIDE SNPs with exclusively aligned enrollment to ensure, first, that all enrollees are covered with the same scope of benefits and, second, that the plans implementing unified grievances and appeals offered a sufficiently substantial range of Medicaid benefits to make the unification of Medicare and Medicaid processes meaningful for beneficiaries and worthwhile for States and plans.

Because the landscape of integrated plans has evolved in the past several

years, we believe there are integrated D–SNPs other than FIDE SNPs and HIDE SNPs for which a unified grievance and appeals process is feasible. Expanding the process to these plans would simplify the grievance and appeals steps for beneficiaries enrolled in these plans for their Medicare and Medicaid benefits and extend the protection of continuation of benefits pending appeal as described in § 422.632 to additional beneficiaries. Accordingly, we proposed, effective January 1, 2023, to expand the definition of the term applicable integrated plan to include an additional type of D–SNP and the affiliated Medicaid managed care plan subject to the rule.

We proposed to include as applicable integrated plans certain combinations of Medicaid managed care plans and D–SNPs that are not FIDE SNPs or HIDE SNPs but meet three other conditions. First, State policy must limit the D–SNP's enrollment to beneficiaries enrolled in an affiliated Medicaid managed care plan that provides the beneficiary's Medicaid managed care benefits. Second, each enrollee's Medicaid managed care benefits must be covered under a capitated contract between (1) the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization, and (2) a Medicaid MCO or the State Medicaid agency. Third, the Medicaid coverage under the capitated contract must include primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C) and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and must include at least one of the following: Medicaid home health services (as defined in § 440.70), Medicaid medical supplies, equipment and appliances (as described in § 440.70(b)(3)), or Medicaid nursing facility services. The affiliated Medicaid MCO in which all of the D–SNP's enrollees are also enrolled in this scenario would also be included in our proposed expansion of applicable integrated plans. As a result, the following arrangements would be applicable integrated plans under our proposal, where both plans include membership that is fully aligned between the D–SNP and an affiliated MCO: (1) A D–SNP and affiliated Medicaid MCO where the D–SNP holds a contract with a separate Medicaid MCO to cover all capitated managed care benefits in the State and the separate Medicaid MCO holds the contract with the State for those benefits (2) a D–SNP and affiliated Medicaid MCO where the affiliated Medicaid MCO holds a contract with the State for the capitated Medicaid benefits.

Where each of these conditions is met, enrollees receive all of their Medicare and Medicaid benefits that are available through managed care in the State through a D–SNP and affiliated Medicaid managed care plan.

We proposed to reorganize the definition of applicable integrated plan in § 422.561 by adding new subsections to the definition in § 422.561 to show separate definitions before and after January 1, 2023. The proposed definition after January 1, 2023, expands the universe of applicable integrated plans to include a D–SNP and affiliated Medicaid managed care plan that meets these three criteria. Under the proposed revisions to § 422.561, current paragraphs (1) and (2) would become paragraphs (2)(i)(A) and (B) and apply before January 1, 2023. Proposed new paragraph (2) of the definition would apply beginning January 1, 2023, and would include the current definition and the proposed new category of D–SNPs and affiliated Medicaid managed care plans that would qualify as an applicable integrated plan.

Comment: We received numerous comments in support of our proposal to expand the unified plan-level appeals and grievance processes to cover additional D–SNPs and enrollees where the State Medicaid managed care program may have carve-outs of LTSS and behavioral health services that prevent the plans from qualifying as FIDE or HIDE SNPs. In support of our proposal and covering more enrollees with the unified procedures, several commenters noted that the unified processes are simpler and easier to navigate for enrollees and will expand access to Medicare services while an appeal is pending. A commenter also noted that our proposed benefit coverage criteria for affected plans are largely areas where overlap is most common, including specifically durable medical equipment and home health. Some commenters, while supportive of our proposal, encouraged CMS to extend the unified processes to additional D–SNPs to cover more enrollees, including D–SNPs that do not have exclusively aligned enrollment.

Response: We appreciate the broad support for our proposal to expand the definition of applicable integrated plans to encompass more plans and cover more enrollees. We agree with those commenters who stated that the unified processes are clearer and easier to navigate for enrollees and provide additional benefits such as continuing Medicare services while an appeal is pending. As we noted in the April 2019 final rule (CMS–4185–F), we do not think it is feasible to align appeals and grievance processes where the D–SNP is not affiliated with the Medicaid MCO covering the enrollee's Medicaid benefits. This includes a plan where some enrollees are aligned but not all. We will continue to monitor for additional opportunities for streamlining and clarifying the process for enrollees. We also remind D–SNPs that they have obligations under § 422.562(a)(5) to assist enrollees with obtaining and appealing Medicaid benefits covered by Medicaid, including when those Medicaid benefits are covered by unaffiliated Medicaid managed care plans or Medicaid FFS programs, as discussed in the April 2019 final rule (84 FR 15723), and that States may include additional integration requirements in their State Medicaid agency contracts with D–SNPs.

Comment: Some commenters, while supportive of our proposal, requested that CMS delay the implementation date. A commenter also asked how CMS would work with States that resist modifying appeals and grievance procedures to comply with the rule.

Response: We acknowledge that plans newly covered by the definition of applicable integrated plan will have less than a year to ensure that they have appropriate processes in place. However, most of the plans that we anticipate will be covered by the revised definition in 2023 currently operate as MMPs in California, and thus have several years' experience operating very similar unified appeals and grievance processes. With the transition of Cal MediConnect, we would like for enrollees who transition to D–SNPs and MCOs operated by the same parent organization to continue to benefit from the unified appeals and grievance processes that they have come to know in Cal MediConnect. We also note that materials and guidance already exist for applicable integrated plans [49] and the Medicare-Medicaid Coordination Office provides technical assistance to States on integration issues. We will continue to engage States, plans, and other stakeholders as we implement the unified appeals and grievance processes for additional plans, particularly in

[49] The Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Coverage Decision Letter (Form CMS–10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs.*

California. We are also committed to continuing our work with States to gather and disseminate best practice information and to engage stakeholders to ensure a successful implementation.

Comment: Some commenters requested clarification, or through their comments suggested a need for clarification, with respect to whether the applicable integrated plans must have exclusively aligned enrollment to be covered under our proposed expansion of the definition of applicable integrated plans. A few commenters specifically suggested that we apply the applicable plan definition to HIDE SNPs, in addition to FIDE SNPs.

Response: We clarify that only D–SNPs with exclusively aligned enrollment, as defined in § 422.2 as those D–SNPs where State policy limits enrollment to full-benefit dual eligible individuals also covered by the affiliated Medicaid managed care organization, will be newly covered by the expanded definition of applicable integrated plans. Exclusively aligned enrollment, as a practical matter, generally refers to HIDE SNPs and FIDE SNPs. In this rule we are including in the definition of applicable integrated plans a subset of D–SNPs that are not HIDE SNPs or FIDE SNPs but still share membership with the Medicaid MCO. Plans covered under the existing definition of applicable integrated plans at § 422.561, meaning FIDE and HIDE SNPs that have exclusively aligned enrollment, will continue to be applicable integrated plans.

Comment: Several commenters opposed finalizing our proposal based on the misunderstanding that the unified procedures would apply to benefits beyond those covered by the D–SNP and Medicaid capitated contracts, potentially making the unified processes unworkable for plans. A few commenters requested clarification on how Medicaid benefits that are carved out of managed care in a State would be covered by the unified appeals and grievance process, and suggested that CMS facilitate data sharing between States and plans so that plans know what Medicaid benefits are covered and what the State requirements are for processing Medicaid appeals. A commenter also questioned the value of unified appeals and grievance processes that do not cover all of an enrollee's benefits due to benefits being carved out of managed care in the State.

Response: The Medicaid benefits covered by the applicable integrated plan will be delineated as covered benefits in the Medicaid managed care contract that the D–SNP has with the State Medicaid agency or other Medicaid MCO. These will be the only Medicaid benefits subject to the unified appeals and grievance process. To the extent that the Medicaid MCO covering the Medicaid managed care benefits is not the same legal entity as the D–SNP, both the Medicaid MCO and the D–SNP must collaborate to implement a unified appeals and grievance process to cover the enrollees' full capitated Medicaid and Medicare benefits, and ensure they are complying with the regulations at §§ 422.629 through 422.634. The appeals and grievances processes for Medicaid benefits that are not capitated to the applicable integrated plan (that is, the plan is not responsible for covering) remain unchanged. For example, if an enrollee appeals the denial of a Medicaid service that is carved out, that appeal would continue to be processed and decided through the State's appeal process as it is today. Similarly, Medicare benefits that are not covered by the D–SNP, specifically hospice benefits, acquisition costs of kidneys for transplant, and certain new benefits that are the subject of an NCD or legislative change in benefits, will not be subject to the unified appeal and grievance process. Benefits that are not covered by the D–SNP or MCO contract will not be covered by the unified grievance and appeals procedures. However, we believe that bringing as many benefits as the plans cover, under the MA contract and under the capitated contract for Medicaid managed care benefits, into the unified procedures still benefits the enrollee by providing the enrollee a single pathway for appeals and grievances for those overlapping benefits, as opposed to separate paths for appeals and grievances based on Medicare or Medicaid coverage. We note that, with respect to the workability of unified appeals and grievance procedures generally, 95 applicable integrated plans in eleven states are currently operating, and we have heard very few questions or concerns. We also reiterate the requirement for all D–SNPs to assist enrollees with obtaining, including appealing, access to all Medicaid benefits, including those that the plan does not cover, per § 422.562(a)(5).

Comment: We received a comment requesting that applicable integrated plans be permitted to use the MA Integrated Denial Notice for ease of plan process and for less enrollee confusion. Another commenter raised questions about the impact of the unified processes on Part C reporting.

Response: We decline to allow applicable integrated plans to use the Integrated Denial Notice (Form CMS–10003–NDMCP) and note that we have issued a specific denial notice for applicable integrated plans, the Coverage Decision Letter (Form CMS–10716). The Coverage Decision Letter[50] is tailored to the unified process and appeal rights and covers the requirements at § 422.631. It is currently in use by existing applicable integrated plans. We have not heard concerns about difficulties in using this notice or confusion on the part of enrollees. As far as Part C reporting requirements, we can confirm that we previously reviewed these requirements and made minor adjustments prior to the implementation of the unified appeals and grievance processes in 2021.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendment to the definition of applicable integrated plans in § 422.561 with slight modifications to increase clarity. We are revising the definition to be clearer where there are references to other paragraphs within the definition and to clarify in paragraph (2)(ii)(C) that, in addition to primary care and acute care (including Medicare cost-sharing), the capitated contracts for Medicaid coverage must cover at a minimum, one of the following categories of Medicaid benefits: Home health services as defined in § 440.70 of the chapter, medical supplies, equipment, and appliances as described in § 440.70(b)(3) of the chapter, or nursing facility services as defined in § 440.155 of the chapter.

8. Permitting MA Organizations With Section 1876 Cost Contract Plans To Offer Dual Eligible Special Needs Plans (D–SNPs) in the Same Service Area (§ 422.503(b)(5))

Section 1876(h) of the Act established reasonable cost reimbursement contracts or ''cost contracts,'' as defined at § 417.401, as Medicare contracts under which CMS pays an HMO or competitive medical plan on a reasonable cost basis. By contrast, MA plans bear the risk of coverage of Medicare and supplemental benefits for their enrollees and are paid risk adjusted capitation by CMS. Cost contracts arrange for Medicare services and provide enrollees several flexibilities not offered to MA plan enrollees, such as the ability to enroll in a plan that offers only Part B benefits and to receive health care services outside of the cost contract plan's

[50] The Coverage Decision Letter (Form CMS–10716) can be found at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs.*

network of providers through original Medicare. As of March 2022, approximately 184,000 beneficiaries were enrolled in six cost contracts offered in nine States.[51]

We direct readers to the proposed rule, 87 FR 1878, for discussion of how Federal statute and regulation restrict cost contracts in several ways. We proposed to modify the prohibition at § 422.503(b)(5) on an entity accepting new enrollees in a cost contract plan while offering an MA plan in the same service area applicable to: (1) A parent organization owning a controlling interest in a separate legal entity accepting new enrollees under a cost contract plan, and (2) another separate legal entity owned by the same parent organization as the legal entity accepting new enrollees under a cost contract plan.

As described in our proposed rule, since CMS finalized the policy at § 422.503(b)(5), we have gained more experience relevant to this D–SNP policy decision through the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience conducted in partnership with the State of Minnesota.[52] Three of the seven MA organizations offering Minnesota D–SNPs participating in the demonstration—comprising almost 60 percent of the demonstration enrollment—also sponsored cost contract plans in overlapping counties. To prevent potential disruption to the demonstration, we waived § 422.503(b)(5) for these entities, using our authority under section 1115A of the Act. This waiver avoided the risk that these entities would, instead of closing the cost contract plans to new enrollment where the service areas overlapped with D–SNPs, non-renew their D–SNPs during the demonstration, which would undermine our ability to carry out successfully the model test. In addition, non-renewal of these D–SNPs could potentially have led to large-scale disenrollment from Minnesota Senior Health Options, a D–SNP and Medicaid MCO program with evidence of strongly favorable outcomes for dually eligible older adults.[53]

Although the waiver and model were not designed to test this specific issue, the waiver of § 422.503(b)(5) provided an opportunity to test whether creating an exception for D–SNPs would result in substantial shifts of D–SNP enrollees to cost contract plans offered under the same parent organization. We direct readers to the proposed rule, 87 FR 1878 through 1879, for a more detailed description of the data reported by D–SNPs with cost contract plans in Minnesota. The data from the Minnesota demonstration showed allowing both a D–SNP and a cost contract plan under the same parent organization did not result in a substantial number of enrollees moving from the D–SNP to the cost contract plan.

Based on this evidence, we believe that allowing a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D–SNP or seeks to offer a new D–SNP would not undermine the policy goals that underlie § 422.503(b)(5)—that is, prohibiting entities from steering high-cost enrollees to their cost contract plans and lower cost enrollees to their risk-bearing MA plans. In addition, creating an exception to § 422.503(b)(5) for D–SNPs would allow the entities in Minnesota that currently offer both D–SNPs (through the demonstration) and cost contract plans in the same market to continue enrollment in both plans after the end of the demonstration, thus avoiding potentially significant disruption to Medicare beneficiaries that would result from each MA organization's non-renewal of one of the two types of products. More broadly, the exception removes a regulatory barrier that, in Minnesota and several other States, can impede D–SNPs from entering a market where cost contract plans remain. Therefore, we proposed to revise paragraph § 422.503(b)(5)(i) and (ii) to allow an MA organization to offer a D–SNP and also—

- Offer an 1876 reasonable cost plan that accepts new enrollees;
- Share a parent organization with a cost contract plan that accepts new enrollees;
- Be a subsidiary of a parent organization offering a cost contract plan that accepts new enrollees; or
- Be a parent organization of a cost contract plan that accepts new enrollees.

In our proposed rule, we solicited comment on the proposed exception for D–SNPs and our process for monitoring for unintended consequences. We also explained how we were considering more limited exceptions to the requirements at § 422.503(b)(5) that may more closely fit our policy goal of removing regulatory obstacles to the availability of D–SNPs that further Medicare-Medicaid integration. Specifically, we were considering limiting the exception to:

- D–SNPs designated as HIDE SNPs, as defined at § 422.2, and FIDE SNPs, as defined at § 422.2;
- D–SNPs that only enroll full-benefit dually eligible individuals;
- D–SNPs that charge no beneficiary premium for individuals eligible for the full Part D low income subsidy;
- D–SNPs that are affiliated with cost contract plans that charge premiums for enrollees eligible for the full Part D low income premium subsidy; or
- Combinations of these types of D–SNPs.

We did not propose these alternatives, citing our belief that they would add complexity to the regulation that we did not believe would be necessary to achieve our primary aim of removing regulatory obstacles to the availability of D–SNPs that integrate Medicare and Medicaid services and improve care for dually eligible individuals. However, we solicited comment on whether inclusion of some or all of these additional alternative criteria in the revisions to § 422.503(b)(5) would strengthen the overall policy.

Comment: A few commenters supported our proposal to allow a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D–SNP or seeks to offer a new D–SNP. No commenters opposed the proposal. A few commenters noted that the proposal would ensure continuity of care for Minnesota's D–SNP enrollees as the Minnesota administrative alignment demonstration phases out. A commenter noted that the proposal would reduce potential barriers to integrated care for Medicare and Medicaid, allow for the expansion of coverage options in other geographies, and ease administrative burden on States. Another commenter expressed general support for policies that address barriers to integration across States, particularly in rural areas, and those that apply best practices from demonstrations.

Response: We thank the commenters for their support of this proposal and agree it would reduce barriers to integration of Medicare and Medicaid.

Comment: A commenter expressed support for CMS's close monitoring of

[51] Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract.*

[52] See *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Minnesota.html.*

[53] Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

enrollment, should we finalize the proposed regulation.

Response: We appreciate the commenter's statement. We will monitor patterns of dually eligible enrollment and disenrollment in applicable cost contract plans and D–SNPs. To the extent we see any pattern that suggests that plan sponsors are persuading D–SNP enrollees to move into cost contract plans, we would investigate and pursue corrective actions or additional rulemaking, potentially removing or restricting the exemption finalized in this rule.

Comment: A commenter suggested that organizations should be permitted to offer both a national MA Employer Group Waver Plan (EGWP) option and continue to offer an individual cost contract plan in certain rural areas of the Midwest with limited Medicare options. The commenter posited that cost contract plans and EGWPs would not compete for the same beneficiaries since, unlike cost contract plans, EGWPs are offered specifically to Medicare-eligible retirees of a particular employer.

Response: We thank the commenter for this suggestion. We note that we limited our proposal to D–SNPs operating in the same area as a cost contract plan to remove regulatory obstacles to the availability of D–SNPs that further Medicare-Medicaid integration. Therefore, this comment is not strictly within the scope of the rulemaking, as the proposed rule does not discuss limitations on EGWPs. Although we are not offering an opinion on the merits of the commenter's suggestion, we would clarify that EGWPs need not restrict enrollment to the Medicare-eligible retirees of a particular employer. For example, Chapter 9 of the Medicare Managed Care Manual provides that professional or other types of group associations with members that do not all have the same employer are not precluded from enrolling Medicare beneficiaries in EGWPs, provided the members of the association are eligible for employment-based health coverage. Further, our regulations do not preclude a Medicare beneficiary who would be eligible for an MA EGWP from electing to enroll in a different coverage option, like a cost plan offered in the area where the beneficiary lives. As a result, it is not as clear as the commenter suggests that the concerns underlying our original adoption of § 422.503(b)(5) would not apply in the context of an EGWP.

After consideration of the comments and for the reasons provided in the proposed rule and our responses to the comments, we are finalizing without modification our proposal to allow a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D–SNP, or seeks to offer a new D–SNP.

9. Requirements To Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634)

Section 50311 of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs to unify Medicare and Medicaid appeals and grievance procedures for integrated D–SNPs. We codified the regulations for unified appeal and grievance procedures §§ 422.629 through 422.634 (84 FR 15720). These procedures apply to applicable integrated plans, which are currently defined at § 422.561 as FIDE SNPs and HIDE SNPs with exclusively aligned enrollment. We are finalizing an amendment to the definition of applicable integrated plan in section II.A.7. of this final rule, which will add new categories of applicable integrated plans beginning January 1, 2023. Based on our initial implementation experience and feedback from stakeholders, we proposed several adjustments, clarifications, and corrections to the regulations governing unified appeal and grievance procedures at §§ 422.629 through 422.634.

Comment: Numerous commenters expressed general support of our proposals for updates to the unified appeals and grievance rules with commenters noting the benefits to enrollees of having a single pathway for Medicare and Medicaid appeals and grievances, integrated notices, and access to continuation of benefits while the appeal is pending for Medicare.

Response: We appreciate the broad support for unified appeals and grievance processes and agree that the unified process is simpler and provides more protections for enrollees.

Comment: Several commenters requested that we delay implementation of the proposed changes until at least 2024 to give plans more time to implement the updates, and to provide more time for CMS to release additional guidance and best practices on the unified appeals and grievance processes.

Response: While we acknowledge the commenters' concern, the updates we proposed are relatively minor, so we are not delaying the implementation date.

Comment: We received several comments requesting that CMS work with States to ensure State-specific requirements are clear and conveyed timely, and additional guidance to plans is released. Commenters also requested that CMS share best practices and additional materials about integrated appeals and grievance processes.

Response: We appreciate the commenters' request for clarity. We will make timely updates to the *Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance* [54] to incorporate the updates made in this rule. CMS is also committed to continuing to engage States, plans, and other stakeholders as we gather and disseminate best practice information, providing technical assistance on integration issues as needs arise.

Comment: Several commenters proposed changes to the existing unified and grievance rules. A commenter suggested that CMS revise § 422.629(e) to require plans to assist providers in filing appeals. A commenter suggested additional information should be required to be included in each organization determination, some of which is already included (for example, the enrollee's right to get a free copy of the information used in making the decision and how to get it and how to continue services while and appeal is pending, and receiving the notice in alternate formats), and details on the second level appeals process (to the Independent Review Entity (IRE) or a State fair hearing). A commenter requested that we add additional specificity on how plans should consider, approve, and provide for appeals of reasonable accommodation requests. A commenter requested clarification on how continuation of benefits work while and appeal is pending. A commenter requested changes to § 422.633(e)(3) to no longer allow circumstances where an enrollee's payment request appeal may be expedited. A commenter requested clarification related to the language in § 422.633(e)(3) on how a plan should determine if non-payment will create material life or health consequences and how quickly decisions and payments must be processed in these cases.

Response: We appreciate the commenters' suggestions. We note, generally, that these comments are on regulations for which we did not propose changes and therefore are

[54] The Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Coverage Decision Letter (Form CMS–10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs.*

beyond the scope of this rulemaking. We included an extensive discussion of the unified appeals and grievance process in the April 2019 final rule (84 FR 15727 through 15744) and in the Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. We direct readers to those documents for additional information and explanation of the existing appeals and grievance system rules for applicable integrated plans, and how to operationalize them.[55] We also direct commenters to the current model notices for applicable integrated plans for reference as to what is currently covered in the notices.[56] We also note that this rule does not impact the requirements for applicable integrated plans to continue benefits while an appeal is pending (please see the April 2019 final rule (84 FR 15737) for more information on how continuation of benefits works in the unified process). These continuation of benefits requirements will be applied to additional applicable integrated plans and their enrollees, per our discussion related to the revised, expanded definition of applicable integrated plans in section II.A.7.

We urge commenters to review the April 2019 final rule (84 FR 15741) for a discussion of expedited payment appeals, which provides the rationale for inclusion of the right for an enrollee to request one. In addition, with respect to the language in § 422.633(e)(3) related to considering whether the standard timeframe could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function, we note that all MA organizations and Medicaid managed care organizations must apply this standard today in various contexts of appeals cases, since this language also exists in §§ 422.566, 422.570, 422.584, 438.210, and 438.410.

Finally, we note that MA plans, including D–SNPs, must comply with applicable Federal civil rights authorities. Section 504 of the Rehabilitation Act prohibits disability discrimination and includes requirements for effective communication for individuals with disabilities (45 CFR 84.52), accessibility standards for buildings and facilities (45 CFR 84.22, 84.23), and filing of grievances and complaints (45 CFR 84.61, 84.7).

a. Providing Enrollees Information on Presenting Evidence and Testimony (§ 422.629(d))

We proposed adding additional language to § 422.629(d) to codify in regulation a provision from existing sub-regulatory guidance.[57] We proposed to revise § 422.629(d) to require that, as part of its responsibilities pertaining to an enrollee's presenting evidence for an integrated grievance or appeal, an applicable plan provide an enrollee with information on how evidence and testimony should be presented to the plan. In addition, our proposal would reorganize § 422.629(d) to improve the readability of the provision.

Comment: Several commenters requested that CMS clarify when, in the appeals process, applicable integrated plans should offer enrollees the opportunity to provide live testimony, and how long such testimony should be allowed to be.

Response: We note that the requirement to provide enrollees with an opportunity to present evidence and testimony is an existing rule, at § 422.629(d). This same requirement to provide an opportunity for evidence and testimony also exists in both the Medicaid managed care requirements at § 438.406(b)(4) for appeals, and for MA plans at § 422.586 for reconsiderations. Our proposed update is to require that applicable integrated plans provide enrollees information on how to present the evidence and testimony. For the evidence and testimony to be meaningful to the plan's decision, it must be accepted prior to the plan's decision and taken into account in that decision. The regulation does not set forth a specific amount of time that must be provided for an enrollee to provide evidence, including testimony, but enrollees must be provided a reasonable opportunity and sufficient flexibility in terms of what is presented as needed to provide relevant information.

After consideration of the comments and for the reasons provided in the proposed rule and our response to the comments, we are finalizing this provision as proposed without modification.

b. Technical Correction (§ 422.629(k))

We proposed technical changes to § 422.629(k)(4)(ii) to correct a minor error from the April 2019 final rule (84 FR 15835). We proposed to replace the word ''organization'' with ''reconsideration'' and remove the word ''decision'' from the end of the sentence in § 422.629(k)(4)(ii) for clarity and consistency in the text.

We received no comments on this proposal. For the reasons outlined in the proposed rule, we are finalizing the proposed change without modification.

c. Accommodate State Medicaid Representation Rules (§ 422.629(l))

At § 422.629(l)(1), we proposed adding additional language to codify in regulation current sub-regulatory guidance [58] regarding the appointment of a representative. We proposed to add language to clarify that an enrollee's representative includes any person authorized under State law to accommodate State Medicaid program appointments. We proposed to reorganize paragraph (l)(1) as part of this amendment. Specifically, we proposed to revise paragraph (l)(1)(i) to list the enrollee and to revise paragraph (l)(1)(ii) to list the enrollee's representative, including any person authorized under State law. We also proposed to move the content of current paragraph (l)(1)(ii) that deals with rights of assignees to a new § 422.629(l)(4) as discussed in section II.A.9.d. of this final rule.

Comment: A commenter requested that CMS clarify the types of documentation applicable integrated plans should accept, and if the documentation requirements would be different depending on whether the underlying benefit is covered by Medicaid or Medicare.

Response: We appreciate the commenters' requests for clarity. Applicable integrated plans should treat all appeals and grievances subject to the rules at §§ 422.629 through 422.634, and authorization of representation documentation, the same whether the underlying benefit is covered by Medicare, Medicaid, or both. If the documentation that the applicable integrated plan receives from a representative meets either State Medicaid or Medicare standards for representation, the plan should accept the documentation. For example, even if the underlying benefit at issue in the

[55] The guidance can be found at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DSNPs.*

[56] The Coverage Decision Letter (Form CMS–10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs.*

[57] CMS, ''Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans''. Retrieved from: *https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminationsappealsguidanceaddendum.pdf.*

[58] CMS, ''Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans''. Retrieved from: *https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminationsappealsguidanceaddendum.pdf.*

appeal is covered only by Medicare, and the representation documentation meets State Medicaid representation requirements, the plan should accept the authorization as sufficient. This is consistent with how the appeal processes for applicable integrated plans were designed to take into account differences in Medicaid State programs, be easily navigable by enrollees, and provide unified procedures and processes.

We did not receive any comments recommending changes to this proposal. For the reasons outlined in the proposed rule, we are finalizing this provision without modification.

d. Clarifying the Role of Assignees and Other Parties (§ 422.629(l))

In the April 2019 final rule, we finalized § 422.629(l)(1)(ii) to include assignees of the enrollee and other providers with appealable interests in the proceedings as individuals who could file an integrated grievance, request an integrated organization determination, or request an integrated reconsideration to clarify the rights of non-contracted providers. We therefore proposed to move the content of § 422.629(l)(1)(ii) to new paragraph (l)(4). As noted in section II.A.9.c. of this final rule, we proposed to add new language at § 422.629(l)(1)(ii) in its place addressing who can be an enrollee's representative.

In new paragraph (l)(4) we proposed to clarify which individuals or entities can request an integrated reconsideration and are considered parties to the case but who do not have the right to request an integrated grievance or integrated organization determination. In paragraph (l)(4)(i), we proposed to permit an assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service) to request an integrated reconsideration. In paragraph (l)(4)(ii) we proposed to permit any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding to request an integrated reconsideration.

Comment: A few commenters requested that CMS clarify what an appealable interest means and clarify the language in § 422.629(l)(1)(ii) that provides that ''parties with appealable interest'' may appeal.

Response: We appreciate the commenters' request for clarity and note that we did not propose any changes to the language in § 422.629(l) related to appealable interest (that is, any other provider or entity—other than the applicable integrated plan—who has an appealable interest). This is existing language in § 422.629(l) and in the longstanding MA appeal rules at § 422.574(d). We point commenters to the discussion on § 422.574 in the June 1998 final rule titled ''Medicare Program; Establishment of the Medicare+Choice Program'' (63 FR 35026) which noted that the phrase includes not just the enrollee, but also allows other parties to exercise appeal rights (excluding the MA organization). As noted in that discussion, parties who may have an appealable interest in a case may include certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and the broad category of any other entity determined to have an appealable interest in the proceeding. These parties can continue to have an interest in the proceedings throughout each level of an appeal. We decline to add a definition for this phrase in this rule. In our proposal we are only reorganizing where this language is in § 422.629(1).

We did not receive any comments recommending changes to this proposal. After consideration of the comments and for the reasons outlined in our responses, we are finalizing this provision without modification.

e. Timelines for Processing Payment Requests (§ 422.631)

In the April 2019 final rule, we neglected to specify how the MA ''prompt payment'' rules at § 422.520 governing payment of claims apply to applicable integrated plans.

Accordingly, at § 422.631(d), we proposed to add a new paragraph (d)(3) to require applicable integrated plans to process payment requests according to the prompt payment provisions set forth in § 422.520, which would mirror the current provision at § 422.568(c).

We did not receive any comments recommending changes to this proposal. For the reasons provided in the proposed rule, we are finalizing the proposed amendment without modification.

f. Clarifying Integrated Reconsideration Request (§ 422.633(e) and (f))

We proposed changes to § 422.633(e)(1) to clarify who may file a request for an expedited post-service integrated reconsideration (that is, one that is related to payment). Our proposal would clarify that an enrollee may request an expedited integrated reconsideration related to payment that can qualify as expedited, but a provider's right to request an expedited integrated reconsideration on behalf of an enrollee is limited to pre-service integrated reconsideration requests. We proposed to specify in § 422.633(e)(1)(i) that expedited post-service integrated reconsideration requests are limited to those requested by an enrollee, and in § 422.633(e)(1)(ii) that providers acting on behalf of an enrollee may only request pre-service expedited integrated reconsiderations.

We solicited comment regarding whether allowing a 60-day timeframe for non-contracted provider payment requests where the provider has obtained a waiver of liability from the enrollee would simplify plan operations without adversely affecting beneficiaries or access to care. We noted that any changes to this timeframe would impact § 422.633(f), and the timing for applicable integrated plans to make integrated reconsideration determinations in cases involving payment requests from providers where the provider has obtained and filed a waiver of liability from the enrollee. We also solicited comment regarding whether adopting such a timeframe for non-contracted provider payment requests would conflict with any State-specific Medicaid rules or processes concerning provider appeals.

Lastly, we proposed at § 422.633(f)(3) to add language to clarify that extensions of up to 14 days are available for any integrated reconsiderations (either standard and expedited) other than those regarding Part B drugs. We proposed to exclude integrated reconsiderations about Part B drugs from the authority for extensions in order to be consistent with current § 422.633(f), which provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2). Our current sub-regulatory guidance addresses this as well.

Comment: A few commenters requested that CMS add language clarifying that when providers are appealing on behalf of enrollees, and the services have been rendered and the enrollee is not financially responsible, they should not be doing so for purposes of their own (provider) reimbursement. A commenter also requested that CMS confirm whether enrollees would need to provide a waiver of liability in these cases.

Response: We appreciate the commenters' perspective on this issue, but we decline to add further detail in the rule on this issue. If a provider is acting on behalf of the beneficiary in the appeals process, the provider's motive

for assisting the enrollee is not relevant; beneficiaries are permitted to have a provider act on their behalf consistent with these rules. In addition, a non-contract provider may appeal in their own right consistent with these rules when a waiver of liability is properly filed. If the provider is acting on behalf of the enrollee, the enrollee does not need to provide a waiver of liability. A waiver of liability would only be provided if the non-participating provider is appealing on their own behalf (not on behalf of the enrollee). We decline to add the suggested additional detail to the regulation at this time.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendments to § 422.633(e) and (f) as proposed without substantive modification. We are finalizing a grammatical revision to paragraph (e)(1)(ii).

g. Timeframes for Service Authorization After a Favorable Decision (§ 422.634(d))

We proposed changes, in § 422.634(d), to more clearly describe timeframes for authorizing services in all situations where an applicable integrated plan's decision is reversed. We proposed reorganizing § 422.634(d) to more explicitly address each scenario that an applicable integrated plan would face when effectuating a reversal. In proposed paragraph (d)(1), we proposed to address cases where the applicable integrated plan reverses its own decision in an appeal for services that were not furnished while the appeal was pending. We proposed that an applicable integrated plan must authorize or provide the service as expeditiously as the enrollee's condition requires and within the sooner of: (1) 72 hours from the date of the reversed decision; or (2) 30 calendar days (7 calendar days for a Part B drug) after the date that the applicable integrated plan received the integrated reconsideration request.

We also proposed to include the Part B drug timeframe from § 422.618(a)(3) in § 422.634(d)(1)(ii)(B) to ensure enrollees of applicable integrated plans get the same timely effectuation of a favorable appeal decision on coverage of a Part B drug; this is consistent with how current § 422.633(f) provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing reconsidered determinations regarding Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2), which apply to other MA plans.

In proposed paragraph (d)(2), for the sake of clarity we proposed to place in its own paragraph the requirement for the applicable integrated plan to authorize or provide a Medicaid-covered service no later than 72 hours from the date the plan is notified of a decision reversed by a State fair hearing. We proposed no changes to this effectuation timeline.

Lastly, we proposed to add a new paragraph (d)(3) to require the same timelines for an applicable integrated plan to effectuate reversals by the Medicare IRE, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council as apply to other MA plans at §§ 422.618 and 422.619.

We requested comment on whether the additional language provides clarity to applicable integrated plans on their responsibility to provide a service after an integrated organizational determination or integrated reconsideration is overturned.

Comment: A commenter recommended that § 422.634 more fully integrate the Medicare and Medicaid processes, specifically requesting that the regulations parallel the integrated process in the Massachusetts One Care FAI demonstration since some services are covered by both programs. The commenter further noted, as an example, that the One Care contract requires the IRE to review both the Medicare and MassHealth medical necessity criteria.

Response: We thank the commenter for this suggestion, but we did not propose, and therefore will not finalize, a further integration of the appeals process at this time. We leave open the future possibility of furthering the integration of the unified appeals and grievance process to include the post-plan appeal procedures, as we noted in the April 2019 final rule (84 FR 15743). With respect to the unique aspects of the One Care demonstration three-way contract, though the IRE cannot review Medicaid cases for Medicaid benefits, it does use Medicaid medical necessity criteria, along with Medicare criteria, when reviewing Medicare supplemental benefit cases under One Care because, in the One Care demonstration, Medicare supplemental benefits are defined by State Medicaid criteria. Applicable integrated plans are not subject to the same requirements in designing and offering MA supplemental benefits. We would need to further evaluate whether there are any viable scenarios in which the IRE may be required to review any particular State's Medicaid coverage criteria in reviewing coverage for a Medicare benefit.

Comment: A commenter requested that CMS clarify whether the timeframes in § 422.634 apply to expedited appeal decisions, and whether CMS intends to issue further guidance on timelines for effectuating reversals after the plan has issued an authorization and when the plan seeks next-level review of the initial appeal decision.

Response: Timeframes for applicable integrated plans to effectuate all decisions are covered in § 422.634; this includes effectuation after reversal by the applicable integrated plan, the IRE, a State fair hearing, or at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council. With the amendments made by this final rule, timeframes for effectuation are as follows:

As expeditiously as the enrollee's health condition requires, but no later than:

1. For a reversal by the applicable integrated plan (reversing its integrated organization determination), no later than the earlier of: (1) 72 hours from the date it reverses its decision or, (2) with the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)). For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

2. For reversals by the IRE, in accordance with MA requirements at § 422.618 the applicable integrated plan must, for standard, non-Part B drug, and non-payment cases, authorize the service under dispute within 72 hours from the date it receives notice reversing its determination, or provide the service under dispute as expeditiously as possible no later than 14 calendar days from that date; for standard Part B drug cases, 72 hours from the date it receives notice reversing the determination; and payment cases, pay for the service no later than 30 calendar days from the date it receives notice reversing the integrated organization determination; and, in accordance with MA requirements at § 422.619, for expedited, non-Part B drug cases, authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination, and for expedited Part B

drug cases, authorize or provide the Part B drug no later than 24 hours from the date it receives notice reversing the determination.

3. If a State fair hearing reverses the applicable integrated plan's integrated reconsideration regarding a Medicaid benefit not furnished while the appeal was pending, the applicable integrated plan must provide or authorize the item or service as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination for all cases, both standard and expedited, in accordance with § 422.634(d)(2) (which is the same timeframe as required under Medicaid regulations at § 438.424).

4. For a reversal by an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council, the applicable integrated plan must effectuate a reversal under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

With respect to a MA plan's appeal rights, these proposed changes do not impact plans' appeal rights, and CMS does not anticipate issuing guidance on that topic as a result of this rule. Sections 422.592 and 422.600 of the MA rules apply to applicable integrated plans that have issued an integrated reconsideration that is adverse, in whole or in part, to the enrollee with regard to coverage or provision of a Medicare benefit. We note that § 422.634(b) addresses adverse integrated reconsiderations; this rulemaking does not revise § 422.634(b). An applicable integrated plan, like all other MA plans, must effectuate a decision in favor of the enrollee from the IRE; the plan does not have the authority to appeal the decision to an administrative law judge.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed amendment to § 422.634(d) without modification.

10. Technical Update to State Medicaid Agency Contract Requirements (§ 422.107)

Section § 422.107(c) lists minimum requirements for State Medicaid agency contracts. Paragraph (c)(6) requires that the contract document the verification of an enrollee's eligibility for ''both Medicare and Medicaid.'' We proposed to strike the reference to Medicare in paragraph (c)(6) as it is not essential for the contract between the State Medicaid agency and the D–SNP to document how the D–SNP verifies Medicare eligibility. All MA plans, including D–SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60. See also Chapter 2 of the Medicare Managed Care Manual for additional details.[59]

Comment: Several commenters expressed support for this technical update as it is a logical simplification of the State Medicaid agency contract minimum requirements.

Response: We thank the commenters for their support of this technical update.

Comment: A few commenters recommended that CMS should not finalize this proposal but should retain the contract requirement that a D–SNP must verify an enrollee's Medicare eligibility. These commenters believed that the existing regulatory text clarifies the State's obligation to identify dually eligible individuals and provide MA organizations with information that distinguishes between types of dual eligibility, such as full-benefit, and partial-benefit dually eligible individuals. A few commenters recommend that CMS require States to provide a crosswalk or translations to category identifiers, such as eligibility for Medicare Savings Programs (MSP), needed to manage benefits for enrollees. This would also serve as a tool to better understand differences in dual eligibility categories for D–SNPs, including partial-benefit dually eligible individuals.

Response: We thank commenters for raising their concerns. We note that we did not propose a change to the contract requirement that the D–SNP validate the enrollee's Medicaid eligibility. As noted in our proposal, all MA plans, including D–SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60. See also Chapter 2 of the Medicare Managed Care Manual for additional details. Therefore, it is not essential for the contract between the State Medicaid agency and the D–SNP to document how the D–SNP verifies Medicare eligibility.

We note that § 422.107(c)(2) states that the contract must document the categories and criteria for eligibility for dually eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act. Therefore, the D–SNP contracts with States should describe how States provide D–SNPs with information needed to enroll dually eligible individuals. For example, if a State limits D–SNP enrollment to full-benefit dually eligible individuals, that State should note in the contract with a D–SNP how the D–SNP will determine an enrollee's status. We encourage D–SNPs to discuss with States any issues in obtaining this information.

After consideration of the comments we received and for the reasons outlined in the proposed rule, we are finalizing our proposed amendments to § 422.107(c)(6) to strike the reference to Medicare.

11. Compliance With Notification Requirements for D–SNPs That Exclusively Serve Partial-Benefit Dually Eligible Beneficiaries (§ 422.107(d))

We codified minimum Medicare-Medicaid integration requirements for D–SNPs at § 422.2, stating that a D–SNP must either (i) be a HIDE SNP or FIDE SNP or (ii) meet the additional requirement specified in § 422.107(d) that requires that the D–SNP notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dually eligible individuals, as determined by the State Medicaid agency.

While implementing these minimum integration standards, CMS identified some MA organizations that have separate D–SNP PBPs for partial-benefit and full-benefit dually eligible individuals, which enable the MA organizations to more clearly explain and coordinate the Medicaid benefits that those enrollees are entitled to receive. However, the D–SNP PBPs for partial-benefit dually eligible individuals (hereinafter referred to as ''partial-benefit-only D–SNPs'') have no explicit pathway to meaningfully meet one of the three integration standards under § 422.2. In a partial-benefit-only D–SNP, no plan enrollees are eligible for the minimum set of Medicaid services that a D–SNP must cover to qualify as a HIDE SNP or FIDE SNP. Additionally, there are no full-benefit dually eligible individuals that the plan could identify for notification of hospital and SNF admissions (and no Medicaid services to coordinate post notification) as required by § 422.107(d).

We proposed to largely codify the guidance issued in January 2020[60] that would allow the partial-benefit-only D–

[59] See *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/mc86c02.pdf.*

[60] CMS Medicare-Medicaid Coordination Office, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'', January 17, 2020. Retrieved from: *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

SNP to be considered as meeting the integration requirements. We proposed revising § 422.107(d) to provide that partial-benefit-only D–SNPs are not required to meet the notification requirement in § 422.100(d) when the MA organization also offers a D–SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization.

As discussed in the proposed rule, we believe our proposal is consistent with the minimum integration required by section 1859(f)(8) of the Act because it achieves the same level of coordination with State Medicaid agencies for partial-benefit dually eligible enrollees as would be achieved if there were one D–SNP PBP covering both full-benefit and partial-benefit dually eligible individuals. Additionally, for full-benefit dually eligible enrollees, the two-PBP structure facilitates a higher level of integration of Medicare and Medicaid benefits (for example, where the two-PBP structure would result in more applicable integrated plans with unified appeals processes). We did not anticipate any negative impact for beneficiaries or partial-benefit-only D–SNPs as a result of this rule.

Comment: Some commenters supported this provision, and no commenters opposed it. A few commenters noted the proposal supports continued enrollment of partial-benefit dually eligible beneficiaries in D–SNPs where they have access to additional care coordination. A commenter noted that partial-benefit dually individuals often can experience a change in circumstances making them eligible for the full Medicaid benefit; this proposal that a plan sponsor also operate a D–SNP serving full-benefit dually eligible individuals could be helpful for care continuity in a transition. Another commenter noted that this provision would allow D–SNP sponsors to continue providing supplemental benefits to partial-benefit dually eligible enrollees.

Response: We thank the commenters for their support.

Comment: A commenter noted CMS should continue to allow States the option to authorize an MA organization to offer a D–SNP that enrolls only partial-benefit dually eligible individuals, with the inclusion of the notification requirement in the State Medicaid agency contract, to meet the integration requirements outlined in the BBA of 2018. This commenter noted that as States move to more integrated FIDE SNP or HIDE SNP models for full-benefit dually eligible individuals, they continue to seek opportunities for partial-benefit dually eligible individuals that provide the best level of care for this population, including by allowing these beneficiaries to remain with carriers that do not have a Medicaid contract.

Response: We appreciate the commenter's concern and confirm that a D–SNP that serves partial-benefit dually eligible individuals without a corresponding full-benefit-only D–SNP in the same service area would be able to continue operating as long as the contract with the State Medicaid agency includes the notification requirement at § 422.107(d)(1).

Comment: Another commenter questioned whether, if the proposal is adopted, States could continue to require MA organizations to submit hospital or skilled nursing facility admissions for partial-dually eligible enrollees if such a requirement in the State Medicaid agency contract.

Response: We thank the commenter for their question and confirm that States remain able to use their contracts with D–SNPs to require MA organizations to notify the State Medicaid agency of admissions for partial-benefit dually eligible enrollees.

Comment: A commenter noted that they have concerns about D–SNPs' ability to comply with this requirement due to Federal and State health information privacy laws regarding the disclosure of particular sensitive health information without an individual's consent. The commenter requested that CMS provide comprehensive guidance on how D–SNPs should reconcile the admission notification requirement with the limitations presented by 42 CFR part 2 and State health information privacy laws, especially as they relate to substance use disorder and mental health services. Alternatively, the commenter suggested that CMS amend § 422.107(d) to relieve D–SNPs of the obligation to submit admission notifications when doing so is not authorized by applicable law or would require an enrollee's consent.

Response: We thank the commenter for expressing their concerns. We emphasize that States must implement the notification requirement at § 422.107(d) in a way that complies with all applicable State and Federal laws. We acknowledge there are limitations to D–SNPs' ability to notify States of certain inpatient admissions for high-risk enrollees with substance use disorder, as well as to their ability to coordinate these individuals' care, absent enrollee consent for the disclosure of such information. We encourage D–SNPs to collaborate with their States to identify and address concerns regarding compliance with other statutes and regulations, including the Health Insurance Portability and Accountability Act HIPAA of 1996 and 42 CFR part 2.

We are still gathering information on the initial implementation of the data notification requirement at § 422.107(d). We will use feedback received in response to the request for information described in section III.C. of this final rule and our work with States and D–SNPs to update technical guidance and consider any needed changes to the regulation.

Comment: A commenter expressed concern with enrolling partial-benefit dually eligible individuals in D–SNPs. This commenter noted that there has not been an analysis to determine if the supplemental benefits offered by some D–SNPs are relevant to partial-benefit dually eligible individuals. The commenter urged CMS to undertake such an analysis and establish minimum criteria to ensure that D–SNPs have relevance and value to partial-benefit dually eligible enrollees.

Response: We thank the commenter and will consider an analysis on the relevance of supplemental benefits to partial-dually eligible individuals enrolled in D–SNPs to determine if establishing minimum criteria through rulemaking is warranted.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendments to § 422.107(d) to provide that partial-benefit-only D–SNPs are not required to meet the notification requirement in new § 422.107(d)(1) when the MA organization also offers a D–SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization.

12. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for

coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost-sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709 through 19711). Section 1858(b)(2) of the Act requires a catastrophic limit on in-network and out-of-pocket expenditures for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also referred to as catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. After the MOOP limit is reached, the MA plan pays 100 percent of the costs of items and services covered under Parts A and B.

In the April 2011 final rule (76 FR 21508), CMS established the approach MA organizations must use to track an enrollee's progress toward the plan MOOP limit. Under this policy, the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking the enrollee's progress toward the plan MOOP limit. This approach also applies to D–SNPs. Thus, for any D–SNP enrollee, MA plans currently have the option to count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost-sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. As a result, in practice, the MOOP limit does not cap the amount a State could pay for a dually eligible MA enrollee's Medicare cost-sharing, nor does it cap the amount of Medicare cost-sharing that remains unpaid for providers serving dually eligible enrollees because of the prohibition on collecting Medicare cost-sharing from certain dually eligible individuals and the limits on State payments of Medicare cost-sharing under State lesser-of policies.[61] Thus, MA plans are paying amounts for non-dually eligible enrollees that they do not pay for dually eligible enrollees, even when different enrollees use the same volume of services; States, in certain circumstances, pay cost-sharing for dually eligible enrollees that is otherwise covered by the MA plans for non-dually eligible enrollees; and providers serving dually eligible MA enrollees are systemically disadvantaged relative to providers serving non-dually eligible MA enrollees, which we believe, based on the evidence described below, may negatively affect access to Medicare providers for dually eligible enrollees.

We proposed to revise the regulations governing the MOOP limits for MA plans to require that all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit. This would ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit established by the plan (whether at the annual limit set by CMS under § 422.100(f) or some lesser amount), the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services. As a result, the State Medicaid agency and other secondary payers would no longer be billed for any Medicare cost-sharing for the remainder of the year. To ensure clarity in the regulation text for the policy on what costs are tracked for purposes of the MOOP limit, we proposed to amend the regulations to specify that MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached. In addition, we proposed to amend § 422.101(d)(4) to substitute ''accrued'' for ''incurred'' in the description of how regional plans must track beneficiary out-of-pocket spending towards the MOOP limit. We intend this amendment to have only the substantive affect described here: That cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit by MA plans. This proposal was not intended to and would not change how the word ''incurred'' is otherwise used in the regulation. We believe that using a different term in the regulation text is appropriate to mark this change in policy from the policy, first adopted in the April 2011 final rule, permitting MA organizations not to count towards the MOOP limit any Medicare cost-sharing amounts paid by Medicaid programs and cost-sharing that remains unpaid under current law because the enrollee is a dually eligible individual. We noted that the specific regulatory amendments would have to change if we finalized the MOOP limit provisions from the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002).

For the reasons discussed in the proposed rule (87 FR 1884), we proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(4) to provide that MA organizations are responsible for tracking out-of-pocket spending accrued by enrollees and must alert both the enrollee and the contracted provider(s) if an enrollee has reached the MOOP limit. For purposes of this amendment, accrued cost-sharing includes all Medicare Parts A and B cost-sharing under the plan, regardless of whether the enrollee or another party or entity pays the cost-sharing, and regardless whether the cost-sharing is actually paid. Our proposed regulation text did not distinguish between cost that is left unpaid because the provider is prohibited from collecting cost-sharing from certain dually eligible enrollees or for other reasons. As noted in the proposed rule, in our experience, MA organizations do not impose additional cost-sharing liability above the MOOP limit on their Medicare-only enrollees if some of the pre-MOOP cost-sharing remains unpaid. We received 58 comments on the proposal.

[61] Section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing for QMBs to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third-party payments) equal to the amount a State would have paid for the service under the Medicaid State plan. For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment. See Chapter II, sections E.4 through E.6 of the Medicaid Third Party Liability Handbook at *https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf.*

Comment: We received broad support, including from State Medicaid agencies, beneficiary advocacy organizations, and providers of primary, specialty, hospital, and long-term services and supports, for our proposal to require MA plans to calculate attainment of the MOOP limit based on the accrual of cost-sharing in the plan benefit. The reasons commenters gave for their support mirror the rationale we provided for the proposal in the NPRM.

Supportive commenters noted the proposal would increase payments to providers serving dually eligible MA enrollees with cost-sharing above the MOOP limit and thereby mitigate disincentives to serve dually eligible MA enrollees and increase provider incentives to join D–SNP provider networks. One State commenter noted that the proposal would make it more financially sustainable for physicians to serve dually eligible MA enrollees. One provider commented that the proposed requirement would reduce the amount of bad debt that providers incur when MA plan cost-sharing goes unpaid due to the combination of limits on State cost-sharing payments and prohibitions on providers collecting cost-sharing from certain dual eligible individuals. Another provider organization commented that the proposed revision to how attainment of the MOOP limit is calculated would capture more dually eligible enrollees with very high medical costs and thereby reduce the administrative burden on providers of having to seek State payment of cost-sharing once the MOOP limit was attained. Numerous commenters wrote that they expected the financial benefits to providers from the proposal would improve provider access for dually eligible MA enrollees.

Many commenters supportive of our proposal stated that it would improve health equity by requiring that dually eligible MA enrollees, and the providers who serve them, are treated the same as non-dually eligible MA enrollees under the MOOP policy. A commenter noted that the proposal would effectively ensure that MA plans face the same liability to pay 100 percent of the cost of services over the MOOP limit just as they are required to do for non-dually eligible enrollees.

A number of commenters supported the proposal because they expect it would reduce State expenditures by ensuring the MOOP limit for dually eligible enrollees would be attained by high cost enrollees, thereby limiting State responsibility for payment of cost-sharing. One beneficiary advocacy organization wrote that current policy, by allowing MA organizations to exclude State paid or unpaid cost-sharing by dually eligible enrollees toward attainment of the MOOP limit, represented an unfair burden on State budgets.

Response: We thank the commenters for their support of this proposal. In particular, we are grateful for their comments, based on their experience serving dually eligible individuals as providers, advocates, or State Medicaid agencies, that finalizing the proposal would reduce provider disincentives to serve dually eligible MA enrollees and potentially improve access to care. We agree with commenters that the proposal results in more equitable treatment of dually eligible MA enrollees in administration of the MOOP protection.

Comment: Both MedPAC and MACPAC supported this proposal. MedPAC wrote that MA organizations should administer the MOOP limit in a consistent manner for all MA enrollees. MedPAC also noted that dually eligible beneficiaries may benefit from improved access to care in MA plans that change how they administer the MOOP to be consistent with the proposed requirement. MACPAC supported the proposal as it would ensure that MA organizations rather than States cover cost-sharing for dually eligible MA enrollees above the MOOP limit.

Response: We thank MedPAC and MACPAC for their comments and value their expertise on this issue.

Comment: Many of the opposing comments stated that dually eligible enrollees would receive no benefit from the proposal because providers in MA plans are already prevented from charging QMBs and full-benefit dually eligible individuals for Medicare cost-sharing for Parts A and B services. Rather, these commenters stated that the result of implementing the proposal would be a reduction in supplemental benefits for dually eligible enrollees, particularly enrollees in D–SNPs, as MA organizations would have to increase their bids to pay for effectively providing a MOOP to dually eligible enrollees and as a result have fewer rebate dollars available to fund supplemental benefits. According to these commenters, if CMS finalized the proposal, the supplemental benefits that MA organizations would have to reduce or eliminate as a result would include dental, hearing, vision, transportation, health food and meals benefits, over-the-counter medical items, health home services and care managers, benefits for individuals with serious mental illness, adult day care, tele-physical health, and benefits addressing health care disparities and social determinants of health. A commenter in particular noted an MA organization had recently added a service to address social isolation and, through an Innovation Center model,[62] cash benefits being provided to enrollees in select D–SNPs in contract year 2022. Several commenters also wrote that the additional cost of implementing the MOOP proposal would make it difficult for D–SNPs to offer zero-premium plans as it would reduce rebate revenues now used to pay down Part D premiums.

Commenters provided a range of estimates for the increases in bid costs and rebate reductions that would flow from implementation of the proposal. A commenter cited analysis estimating that the additional cost for Part A and B benefits for D–SNPs if implemented in 2022 would be $23.90 per member per month or a 2.3 percent increase in plan bids. A commenter estimated that its per member costs would be 20 to 25 percent higher than this estimate, while another commenter stated this level additional costs would be shouldered by all D–SNPs. Another D–SNP sponsor projected the proposal would reduce by half the available funds for supplemental benefits. A commenter estimated the added cost could be as high as 2 percent of plan revenue. Another commenter cited the cost of the MOOP proposal estimated in the proposed rule. Some commenters noted that smaller, regional D–SNPs would be less able to absorb these added bid costs than larger MA organizations.

Response: We recognize that implementation of this proposal would raise MA bids for basic benefits, especially for D–SNPs and other MA plans with a high percentage of dually eligible enrollees, and thereby potentially reduce rebates available for a range of supplemental benefits to the extent MA organizations are unable or unwilling to reduce profit margins or other costs to account for the added MA plan costs for services provided after an enrollee meets the MOOP limit. Along with many of the commenters who supported our proposal, we appreciate the value to dually eligible enrollees of certain supplemental benefits offered through D–SNPs and other MA plans. We disagree that the MOOP proposal provides no benefit to dually eligible enrollees. We address the potential benefit to improved provider access later in this rule.

In the proposed rule, using contract year 2022 bid data to estimate the Medicare cost-sharing accrued by dually

[62] For information on the Value Based Insurance Design Model, see *https://innovation.cms.gov/innovation-models/vbid.*

eligible beneficiaries with cost-sharing protections (full-benefit dually eligible and QMB enrollees) above the mandatory MOOP level ($7,550 in 2022), we estimated the cost of Medicare cost-sharing above this MOOP level to be on average $22.99 per member per month. This estimate is very similar to the $23.90 estimate provided by an analysis cited, but not provided, by several commenters. Both estimates are based on D–SNP bid data, and as such already reflect the higher medical costs of dually eligible enrollees.

We believe that for most MA organizations, most (if not all) of the added costs for implementation of the MOOP proposal could be absorbed by reductions in plan profit margins and still allow MA organizations to achieve D–SNP profit margins that are comparable to the overall MA profit margins. According to MedPAC, D–SNPs had average profit margins of 7.8 percent for the 2019 contract year, while the overall MA plan profit margin averaged 4.5 percent.[63] A 2 percent increase in bid costs represents a less-than-two percent increase in revenue, as plan revenue also includes rebate dollars and increases due to risk adjustment of MA payments. Thus, based on recent years of experience, a 2 percent increase in bid costs could be fully absorbed in D–SNP profit margins while still allowing average D–SNP profit margins to exceed average MA plan margins.

We recognize that MA organizations with smaller D–SNP margins, including some regional and nonprofit organizations, may have more difficulty absorbing the full costs of the proposal by reducing margins. MedPAC noted that nonprofit D–SNPs had lower average 2019 gain/loss (profit) margins of 2.5 percent (still higher than the overall nonprofit MA margin of 0.9 percent).[64] Although we value the participation of these organizations in the D–SNP program, we believe that the benefits of our proposal outweigh the downsides, including the differential difficulty that smaller, nonprofit MA organizations may face to come into compliance. Such organizations also have less revenue to comply with a range of MA requirements, including provision of the Part A and B benefit, yet we do not differentiate between the types of MA organizations in requiring delivery of such benefits. In sum, we are not convinced that the added bid costs attributable to the proposal would necessarily translate into reductions in valuable supplemental benefits for dually eligible enrollees. We also do not believe the costs of implementing the MOOP proposal would jeopardize the ability to pay down Part D premiums and offer zero-premium plans. For contract years 2021 and 2022, D–SNPs allocated an average of $7.50 per member per month to pay down the Part D premium to the amounts covered by the Part D Low Income Premium Subsidy, amounts that we believe D–SNPs would be able to continue to allocate as they implement this proposal. Finally, since promulgation of our proposed rule, we issued a final rule with comment period to finalize regulations regarding the MA MOOP and cost-sharing limits for Medicare Parts A and B services titled ''Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost-Sharing Standards'' (CMS–4190–FC4; 87 FR 22290, April 14, 2022) (''MOOP April 2022 final rule''), which will raise the in-network mandatory MOOP limit to $8,300 starting in 2023. This regulatory change will reduce the costs of this proposal to D–SNPs and other MA plans that adopt the mandatory MOOP limit.

Comment: Many commenters opposing this proposal disagreed with CMS that its implementation would improve access to providers in D–SNPs and other MA plans and noted that CMS had provided no evidence of dually eligible MA enrollees having problems with access to providers. A commenter cited data from the Medicare Current Beneficiary Survey that showed that a higher percentage of dually eligible MA enrollees than dually eligible individuals in Original Medicare had a usual source of care (91 percent compared to 86 percent). Other commenters believed that, because D–SNPs and other MA plans must meet CMS provider network access requirements, CMS's concerns about dually eligible enrollees' access to care were misplaced. Another commenter opined that, to the extent that there are problems with access to specialists for dually eligible MA enrollees, the reasons underlying such access problems are more complicated than whether MA plans pay providers 100 percent of the cost of services above the MOOP level, as they do for non-dually eligible enrollees.

Response: We thank the commenters for their input. We recognize that D–SNPs and other MA plans must meet CMS network requirements but note that the number of providers who are participating in Original Medicare is much larger than the number of providers in the network typical of MA plans, and the access problems facing dually eligible individuals in Original Medicare in States where lesser-of policies limit payment of Medicare cost-sharing are well established.[65] According to one study, the reductions in Medicare cost-sharing under these policies decreased the odds that a dually eligible individual would have an outpatient physician visit or mental health treatment visit in comparison to non-dually eligible Medicare beneficiaries.[66] MACPAC found that, relative to non-dually eligible Medicare beneficiaries, lower payment of cost-sharing correlated with a decreased likelihood of evaluation and management visits, use of outpatient psychotherapy, and increased likelihood of using a safety net provider such as an FQHC or rural health clinic.[67] A third study found decreased use of outpatient services among QMB-only beneficiaries and decreased utilization of office evaluation and management services and hospital outpatient services among QMB-plus beneficiaries compared to non-dually eligible Medicare beneficiaries.[68] Although these studies all draw from Medicare FFS data, they establish that Federal and State policies on coverage of Medicare cost-sharing, and the amounts paid providers for Medicare cost-sharing, impact access to care for dually eligible individuals. Our current policy on attainment of the MOOP limit allows for a disparity in MA plan payment of cost-sharing for dually eligible compared to non-dually eligible MA enrollees. We believe that, to the extent that D–SNPs and other MA plans replicate the Medicare FFS structure, including by effectively never providing a MOOP above which the MA organization pays 100 percent of costs, that similar differences in access

[63] See chapter 12 of Medicare Payment Advisory Committee, *March 2021 Report to the Congress: The Medicare Advantage Program: Status Report.* Retrieved from: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch12_sec.pdf.*

[64] Ibid.

[65] See *https://www.kff.org/medicare/report/medicare-advantage-how-robust-are-plans-physician-networks/* MA plan networks on average include 46 percent of physicians in a county, with lower averages for some specialists, such as oncologists, and for ''narrow-network'' plans. By contrast, 97 percent of physicians participate in Original Medicare. See: *https://www.kff.org/medicare/issue-brief/how-many-physicians-have-opted-out-of-the-medicare-program/.*

[66] *https://www.rti.org/sites/default/files/resources/StatePaymentLimits.pdf.*

[67] *https://www.macpac.gov/publication/effect-of-state-medicaid-payment-policies-for-medicare-cost-sharing-on-access-to-care-for-dual-eligibles/.*

[68] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.*

between dually eligible and non-dually eligible would be replicated in MA plans, and especially in D–SNPs that largely replicate Original Medicare in their plan benefits. We are under no illusion that implementation of our MOOP proposal would eliminate all access barriers facing dually eligible MA enrollees, but, to the extent it provides greater parity in plan benefits between dually eligible and non-dually eligible MA enrollees, we are confident that it would at least incrementally improve dually eligible MA enrollees' access to care. As previously noted in this rule, a range of providers commented that they expected parity in payment over the MOOP limit between non-dually eligible MA enrollees and dually eligible MA enrollees would improve access to care.

Because of the strong evidence, cited above, of access challenges for dually eligible beneficiaries (relative to non-dually eligible beneficiaries) in Original Medicare, we are unpersuaded by the MCBS data showing a four percentage point differential between dually eligible MA enrollees who have a usual source of care and their counterparts in Original Medicare. We think the more salient comparison for access to care is between dually eligible and non-dually eligible MA enrollees. We acknowledge that the body of evidence directly comparing access to care in MA between the two cohorts is limited. This is because one important source of data on this issue, the self-reported beneficiary experience measures in the MA CAHPS surveys, is reported at the contract level and thereby often comingles data on D–SNP performance within larger contracts that include non-D–SNP MA plans as well. We are finalizing a policy that can begin to address the scope of available quality measurement data in section II.A.6.a. in this final rule in our discussion of D–SNP-only contracts under proposed § 422.107(e). We note, however, that in the 2022 Star Ratings, 14 percent of the universe of D–SNP-only MA contracts had a low star rating—one or two stars—compared to 10 percent of MA contracts with no D–SNP enrollment on the CAHPS measure C18—Getting Appointments and Care Quickly. Fifty percent of MA contracts with 100 percent D–SNP enrollment had high star ratings on this measure—4 or 5 stars—but 65 percent of contracts with no D–SNP enrollment had high star ratings on this measure. Although imperfect, this data substantiates our concerns that access to and availability of healthcare for dually eligible individuals in D–SNPs is less than that for MA enrollees who are not dually eligible. These concerns support finalizing this provision as proposed.

Comment: A commenter wrote that implementation of this proposal would have a significant impact on D–SNP enrollees, who constitute 35 percent of Medicare beneficiaries in Puerto Rico, and would result in higher premiums and/or reductions in supplemental benefits such as dental coverage and other benefits that address social barriers to health.

Response: We appreciate the commenter drawing our attention to the issues affecting D–SNP enrollees in Puerto Rico but do not agree with this assessment of the potential impact to these enrollees. All Puerto Rico D–SNPs, in the Platino contracts they sign with ASES (Puerto Rico's Medicaid agency), certify that they have no cost-sharing for Medicare Parts A and B services. Unlike States, Puerto Rico does not have a QMB program under which the State pays Medicare cost-sharing for Medicare services provided by these D–SNPs or that provides protections against providers billing for unpaid Medicare cost-sharing under the D–SNP benefit. That means the full cost of Medicare services, both before and after attainment of the MOOP limit, is already paid by the D–SNPs and funded by a combination of Medicare bid and rebate payments for the D–SNP bids and payments from ASES. Therefore, we do not believe this proposal will have an impact on the Puerto Rico D–SNPs' costs for covering Medicare services.

Comment: A commenter noted that there would be minimal to no impact on its provider payments above the MOOP limit because the D–SNP does not charge cost-sharing and pays providers a set percentage of the Medicare fee schedule regardless of the claim. Another commenter stated that FIDE SNPs with a negotiated single fee schedule for providers would also see no impact on provider payments under the MOOP provision.

Response: We thank the commenters for this analysis as it provides an opportunity to better explain our proposal. FIDE SNPs and other D–SNPs that are capitated by the State for Medicare cost-sharing for all their full-benefit dually eligible QMB members have the ability to negotiate a single fee schedule for providers that encompasses both the Medicare and Medicaid responsibility for any claim. If implementation of the proposal has no impact on these D–SNPs' payments to providers above the MOOP, then there should be no increase in these D–SNPs' bids unless there is a reduction in the capitation rate that the Medicaid agency pays for coverage of Medicare cost-sharing and MA organizations must make up the difference in their bids. We note that less than one third of total D–SNP enrollment are in D–SNPs with exclusively aligned enrollment that are capitated by the State Medicaid agency for Medicaid payment of cost-sharing for Medicare Part A and B benefits, and a smaller proportion still of dually eligible enrollees in all MA plans are in such D–SNPs. We do not know, however, whether all these D–SNPs with exclusively aligned enrollees negotiate a single fee schedule for Medicare services encompassing both Medicare and Medicaid payments.

Comment: A few commenters believed implementation of the proposal would have a negative impact on MA organizations' ability to negotiate value-based payment arrangements with providers or implement State-directed value-based payment initiatives in connection with Medicaid managed care contracts also held by the MA organizations. Another commenter wrote that the MOOP provision would incentivize providers to run unnecessary tests and procedures to speed their patients' progress toward the MOOP limit, after which the providers would receive full payment from the MA plan for the care they provide. A separate commenter stated that the chief beneficiaries of the proposal would be dialysis providers that have a duopoly on dialysis clinics and providers of Part B drugs and CMS should determine which providers would benefit from the MOOP proposal and whether access to these providers would be improved.

Response: We thank commenters for this input but do not find it persuasive. We do not believe changes to the calculation of the MOOP to take into account the particular cost-sharing circumstances for dually eligible enrollees and making effective the requirement that MA plans pay 100 percent of the cost of services above the MOOP limit would in any way limit the ability of MA plans to negotiate value-based payment structures with their providers. As proposed and finalized, this policy would in no way restrict the ability of MA organizations to negotiate payment rates with their providers, including the ability to negotiate capitated or semi-capitated payment arrangements. Regarding incentives for providers to perform unnecessary tests and procedures to advance patients towards the MOOP, we expect that MA organizations would employ appropriate utilization management and fraud prevention techniques to prevent any such provider behavior, both to ensure program integrity and for the

health of their dually eligible enrollees. Lastly, we are not in a position to judge whether special classes of providers are deserving of the extra payments that may flow to them under this new policy, but do not believe the evidence supports the belief that dialysis providers and providers of Part B drugs will be the primary recipients of additional MA payments above the MOOP limit. Nor does this amendment to how costs are counted toward the MOOP impact the relative market power of MA organizations and providers in connection with their respective ability to negotiate payment arrangements.

Finally, we note that skilled nursing facilities may also be recipients of higher payments for their dually eligible patients that have exceeded the MOOP limit. These higher payments may reduce SNF incentives to encourage their patients to disenroll from their MA plan, despite the prohibition on such provider interference with beneficiary plan choice, a practice described to CMS in anecdotal reports.[69] To the extent dually eligible enrollees remain in their MA plan, particularly in FIDE SNPs, after a SNF admission, the MA organization would be better able to participate in discharge planning and ensure the individual has the appropriate supports to return to the community.

Comment: A few commenters objected to the proposal, citing their belief that it would use Medicare funds to subsidize Medicaid, by requiring MA organizations to pay 100 percent of the costs of care after cost-sharing in the plan benefit had accrued to reach the MOOP limit, substituting Medicare dollars in the form of MA capitation payment for the state Medicaid dollars that now continue to pay cost-sharing for dually eligible enrollees with no effective limit provided by the MOOP.

Response: We disagree that the provision constitutes an inappropriate subsidization of Medicaid by Medicare. Any policy that impacts Medicare coverage of services or payment rates for which Medicaid is responsible to pay dually eligible individuals' cost-sharing necessarily has the impact of increasing or decreasing the amount of cost-sharing paid by Medicaid. The fact that this proposed Medicare policy does result in significant savings to States should not by itself constitute a reason not to pursue it.

Comment: A commenter disagreed with the concern we expressed in the proposed rule that the current policy may not be fully consistent with section 1902(a)(25)(G) of the Act by allowing MA organizations to calculate attainment of the MOOP limit differently for non-dually eligible beneficiaries, for whom MA organizations accrue all cost-sharing in the plan benefit towards the MOOP limit, from dually eligible enrollees, for whom no cost-sharing in the plan benefit, whether paid by the State or unpaid because of prohibitions on collection of such cost-sharing, counts toward attainment of the MOOP. As the commenter notes, section 1902(a)(25) of the Act requires Medicaid State plans to prohibit any insurer from taking into account that an individual the insurer covers is eligible for or receives assistance from Medicaid. The commenter acknowledges that the current policy does allow MA organizations to take into account dually eligible enrollees' receipt of Medicaid assistance by disregarding any the cost-sharing actually paid by the State. However, the commenter stated that dually eligible enrollees' cost-sharing is similarly not counted towards attainment of the MOOP, not because of the enrollee's eligibility for Medicare, but because it is in fact not owed by the enrollee or ever paid, in contrast to other MA enrollees who typically are billed for cost-sharing and pay those bills. The commenter suggested that CMS's proposal was internally inconsistent by requiring MA plans to count towards the MOOP limit cost-sharing that remains unpaid because the enrollee is also eligible for Medicaid, which requires the MA plan to take into consideration Medicaid eligibility in a way that is not aligned with section 1902(a)(25) of the Act. The commenter also suggested, if CMS should change the basis on which MA plans calculate attainment of the MOOP limit, the agency should only require MA organizations to count amounts the State actually pays in cost-sharing toward attainment of the MOOP.

Response: We appreciate the commenter's acknowledgement that MA organizations' disregard of Medicaid cost-sharing does in fact ''take into account'' their enrollees' receipt of Medicaid benefits in administration of the MOOP limit. We do not agree that the disregard of cost-sharing that is unpaid because of the protection afforded dually eligible beneficiaries does not similarly raise concerns about section 1902(a)(25)(G) of the Act, which also requires the State plan to prohibit insurers' administration of plan benefits because of an individual's eligibility for Medicaid. As the commenter recognizes, the protection against being billed Medicare cost-sharing is conferred on the individual by virtue of their eligibility for QMB or full Medicaid benefits. Further, disregarding unpaid cost-sharing in calculating attainment of the MOOP has the effect of delaying attainment of the MOOP and shifting costs onto Medicaid that would not be borne by non-Medicaid enrollees, which is the very scenario that section 1902(a)(25)(G) is designed to prevent. For this reason, we disagree with the alternative suggested to have MA organizations count only Medicaid-paid amounts toward the MOOP limit. This would undermine the goal of providing the same plan benefit under the MOOP policy for both dually eligible and non-dually eligible MA enrollees; the limits of State cost-sharing payments under lesser-of policies would mean that the effective MOOP limit for dually eligible MA enrollees in most States would be much higher than for non-dually eligible MA enrollees. Finally, we note that, while it is true that MA beneficiaries typically do pay their MA cost-sharing, it is also true that dually eligible beneficiaries, despite the prohibition against providers billing them for cost-sharing, do get billed and do pay such cost-sharing.[70] The current policy, under which MA organizations assume no dually eligible enrollee pays cost-sharing, might not result in counting these vulnerable beneficiaries' payment of improperly billed cost-sharing toward the MOOP limit.

Comment: A few commenters questioned whether CMS's proposal was usurping the authority Congress granted States to establish lesser-of policies. Other commenters questioned whether, by changing the method MA plans must use to calculate the MOOP limit, CMS was superseding the authority granted by Congress in MIPPA to establish state Medicaid agency contracts with D–SNPs.

Response: We respectfully disagree with the commenters' assertions that this proposal would usurp or supersede authority granted States by Congress. Our proposal would not limit State flexibility to establish rates, including lesser-of rates, that set limits on state Medicaid payment of Medicare cost-sharing. Instead, we proposed requirements for the MOOP limits established by MA plans and how cost-sharing is counted toward the MOOP limit, particularly with regard to cost-sharing for dually eligible enrollees. As Medicare is primary to Medicaid, the policy necessarily impacts Medicaid as

[69] *https://www.cms.gov/files/document/ltcfdisenrollmentmemo.pdf.*

[70] See: *https://www.cms.gov/sites/default/files/repo-new/42/Access_To_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.*

a secondary payer. We are not superseding State authority to establish the methods a State requires D–SNPs that operate in the State to employ in the administration of Medicaid's responsibility for cost-sharing. Again, our proposal is focused on how MA organizations administer the MOOP limit, which is a benefit required, under §§ 422.100(f) and 422.101(d), from MA plans in connection with basic benefits (that is, the Medicare Part A and Part B benefits covered by MA plans). The authority Congress has granted under section 1859(f) of the Act States for their D–SNP contract is not limited to administration of Medicaid benefits that D–SNPs are contracted to provide. Such contracts can include requirements on D–SNPs relative to the Medicare cost-sharing they impose in plan benefits; our proposal does not impinge on or limit that authority.

Comment: A few commenters questioned whether CMS has the legal authority to impose a mandatory MOOP limit on any MA plan other than regional PPOs, which are the only MA plans that the Part C statute specifically requires to have MOOP limits. A commenter wrote that CMS instituted a MOOP requirement for all plans on the basis of its authority to ensure MA organizations do not design plan benefits to discourage enrollment by Medicare beneficiaries with higher costs. The commenter notes that CMS provides no evidence that the current policy on dually eligible individuals' attainment of the MOOP is discouraging enrollment in MA plans or D–SNPs. Moreover, the commenter argues that the rationale we provided for this proposal is not the same as the rationale underlying the MOOP requirement.

Response: The overall legal underpinning for the current MOOP rules, established through notice-and-comment rulemaking over a decade ago, is beyond the scope of this final rule. In adopting the MOOP requirements in the April 2010 final rule titled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19804), CMS also relied on its authority in section 1856(b)(1) of the Act to establish standards for MA organizations and MA plans and in section 1857(e)(1) of the Act to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program. CMS's authority under the statute for the MA program is not limited to implementing only the specific requirements listed in the statute.

Regarding the assertion that CMS has provided no data to support the claim that the current way that some MA organizations calculate attainment of the MOOP limit for dually eligible individuals substantially discourages enrollment by these individuals, our proposed rule makes no such claim to justify our proposal. In addition to the responsibility to deny an MA plan design that we determine is likely to substantially discourage enrollment by certain beneficiaries, CMS also has authority under section 1854(a) of the Act to negotiate MA bids similar to the authority given the Office of Personnel Management to negotiate health benefits plans under the Federal Employees Health Benefits Program, and we are not obligated to accept every bid. CMS also has established the authority, under § 422.100(f)(2) to review and approve MA benefits and cost-sharing to ensure that MA organizations are not designing benefits to discriminate against beneficiaries or inhibit access to services. Our MOOP proposal, which requires that MA organizations' MOOP limit is administered the same way for dually eligible enrollees and non-dually eligible enrollees, is consistent with this authority. In addition, by preventing a method of adjudicating the MOOP benefit that now results in providers serving dually eligible enrollees never receiving the same level of payment as providers serving non-dually eligible enrollees, our proposal prevents MA organizations from implementing a cost-sharing structure that has the potential to inhibit access to services for dually eligible enrollees. In addition, § 422.100(d)(2)(i) requires MA organizations to offer uniform benefits and level of cost-sharing through the plan's service area. This is not the case when the MA organization adjudicates attainment of the MOOP one way for non-dually eligible beneficiaries (by accruing all cost-sharing in the plan benefit) and another way for dually eligible beneficiaries (by accruing none of the cost-sharing accrued by dually eligible beneficiaries with cost-sharing protections). Similarly, D–SNPs that enroll both dually eligible individuals with cost-sharing protections and dually eligible individuals whose only Medicaid benefit is payment of their Part B premiums, also do not adjudicate the MOOP uniformly. For the dually eligible enrollees with cost-sharing protections, none of the cost-sharing accrues toward the MOOP limit; for the dually eligible enrollees without such projections, all of the cost-sharing in the plan benefit accrues toward the MOOP limit.

Finally, we have learned since promulgation of the proposed rule that some MA organizations have used the flexibility afforded to MA organizations with a lower voluntary plan MOOP to design a benefit with higher service-specific cost-sharing, even though the MOOP limit is never attained because no cost-sharing in the D–SNP plan benefit counts toward the MOOP. For example, some MA organizations have established D–SNPs with a lower, voluntary MOOP and subsequently raised cost-sharing for other Part A and B services above levels that are actuarially equivalent to the Original Medicare benefit for those services. These MA organizations have raised cost-sharing for services including inpatient and mental health hospital stays and imposed cost-sharing for home health services. In D–SNPs for which the bid information shows no cost associated with payment of cost-sharing above the MOOP limit, indicating that the MOOP is almost never attained by enrollees, these MA organizations have raised cost-sharing for emergency and post stabilization services. We believe this practice is manipulative of our benefit review process and has the potential to violate the requirement at § 422.254(b)(4) that MA plans provide a benefit that is at least actuarially equivalent to Original Medicare. Implementation of our MOOP proposal would ensure that the flexibility we allow to raise service-specific cost-sharing to encourage use of the lower, voluntary MOOP would ensure that use of the MOOP limit actually limited cost-sharing under the plan benefit.

Comment: A few commenters stated that they were grateful that the proposal did not exclude charitable contributions to cost-sharing from applying toward the MOOP limit. A commenter asked CMS to identify what beneficiary costs may be waived by providers. Another commenter noted that the proposal did not specifically exclude cost-sharing paid by pharmaceutical manufacturer patient assistance programs from counting as cost-sharing toward the MOOP limit and requested that similar pharmaceutical manufacturer assistance count toward the MOOP limit employed by Marketplace plans.

Response: Although it is accurate that charitable contributions to MA enrollees' cost-sharing would count toward the MOOP limit for MA plans under our proposal, we remind commenters that the reduction or waiver of cost-sharing by providers implicates the Federal Anti-kickback Statute (AKS), found in section 1128B(b) of the Social Security Act

(Act), and the civil monetary penalties provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP), found in section 1128A(a)(5) of the Act. Whether any particular arrangement violates the AKS or the Beneficiary Inducements CMP would be based on the specific facts and circumstances. Similarly, subsidies provided by pharmaceutical manufacturer assistance programs that induce the purchase of federally reimbursable items, such as drugs paid for by Medicare Part B, also implicate the AKS. A subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer assistance program may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary's selection of a particular provider, practitioner, or supplier. The comments seeking CMS guidance on what beneficiary costs may be waived by providers and seeking to require that pharmaceutical manufacturer patient assistance counts toward the MOOP limit used by Marketplace plans are out of the scope of this rule.

Comment: Other comments we received asked for the MA MOOP protection to be extended to Part D, that CMS increase payment rates to MA plans, that CMS change the cost-sharing applicable to physical therapy and that CMS allow hospitals to collect bad debt for unpaid cost-sharing under MA plans.

Response: These comments are outside the scope of this rulemaking.

Comment: Several commenters asked CMS to prohibit States from using lesser-of policies in establishing the amounts paid for Medicare cost-sharing.

Response: We do not have the statutory authority to prohibit States from using lesser-of policies in establishing the amounts paid for Medicare cost-sharing.

Comment: We received numerous comments concerning how MA organizations would operationalize the proposal and how States would know when the MOOP limit was attained and should no longer be billed by providers for dually eligible MA enrollees' cost-sharing. Several commenters questioned how they would obtain information on non-Medicaid secondary coverage in accruing cost-sharing toward the MOOP limit. A few commenters questioned how the cost-sharing that has accumulated toward the MOOP would be transferred to another MA organization if enrollees switch plans mid-year. A commenter objected to the proposed requirement to notify dually eligible beneficiaries when the MOOP limit is reached, stating that it would be confusing to these enrollees because they do not themselves owe cost-sharing. The commenter also opposed a requirement that MA organizations notify providers that an enrollee has reached the MOOP limit because providers have other means to access MOOP information.

Response: We thank the commenters for this input. MA organizations would not need to engage in tracking non-Medicaid secondary coverage because all cost-sharing, whether or not paid by secondary coverage, that is in the plan benefit package for Parts A and B services would accumulate toward the MOOP limit. MA organizations can rely entirely on the claims for services they receive from providers and accumulate the cost-sharing in the plan benefit for those services toward the MOOP limit.

Longstanding CMS guidance, as described at 50.1 of Chapter 4 of the Medicare Managed Care Manual, is that when an enrollee switches to another plan of the same type (for example, from one HMO to another HMO) offered by the same MA organization, their accumulated annual contribution toward the annual MOOP limit in the previous plan to date is to be counted towards their MOOP limit in the new MA plan. As applicable, this transfer of MOOP applies to both in-network and out-of-network MOOP. The MOOP limit is not now a transferrable benefit when a MA enrollee changes to a plan offered by a different MA organization. The cost-sharing that counts toward the MOOP limit starts anew with the cost-sharing that is incurred or accrued under the new plan offered by the different MA organization. Our proposal does not change that.

We disagree that we should eliminate the requirement to alert dually eligible enrollees and providers when enrollees have reached the MOOP limit. We note that this requirement is already in § 422.101(d)(4) (and has been for several years) and was explicitly added to § 422.100(f)(4) and (5) in a recent MOOP April 2022 final rule, CMS–4190–FC4. Our proposal only changes how attainment of the MOOP limit is calculated. We will consider for future rulemaking whether there are circumstances where alerting enrollees may be unnecessary. In the interim, we believe providing the identical notification to a dually eligible beneficiary with cost-sharing protections as is provided to a non-dually eligible enrollees has the potential to be confusing. The notification to dually eligible enrollees should be tailored to their circumstance. If the dually eligible enrollee should not ever be charged cost-sharing by MA plan providers, any notification alerting these enrollees that they attained the MOOP limit should reflect that. Attainment of the MOOP limit can be accurately described by telling enrollees they have reached the stage in their benefit when their plan will pay all the cost of your care, and that their providers no longer need to bill Medicaid.

We disagree that providers serving dually eligible enrollees should not be alerted when the MOOP limit is attained, a requirement that was finalized in CMS–4190–FC4 at § 422.100(f)(4) and (f)(5)(iii). Alerting providers that the MOOP limit has been attained, that the MA organization will cover 100 percent of the cost of services for the remainder of the year, and that State Medicaid agencies should no longer be billed for Medicare cost-sharing, is essential for administration of the MOOP limit. Remittance advice indicating attainment of the MOOP limit and the absence of any additional cost-sharing charges may fulfill the requirement. If providers have accurate remittance advice from MA organizations, they will have no claim for Medicaid payment of Medicare cost-sharing over the MOOP limit to submit for State payment.

We note that remittance advice to providers serving dually eligible MA enrollees with cost-sharing protections under the MA plan—QMBs, SLMB+, and other full-benefit dually eligible enrollees—should explain that no cost-sharing may be billed whether the enrollee has attained the MOOP limit or not.

Comment: Numerous commenters urged CMS, if we finalize the proposal, to delay the effective date until 2024 or 2025.

Response: We disagree that a delay is necessary for MA organizations to implement the proposal or to submit accurate bids for contract year 2023 that take this change into account. MA organizations already have experience projecting costs and utilization for their enrollees for purposes of bids and accumulating the cost-sharing accrued under the plan benefit; annual bids require projections of cost and utilization and MA plans must accumulate cost-sharing and process claims after the MOOP limit is reached now for non-dually eligible enrollees. There is also sufficient time before the start of the plan year to develop tailored notices for dually eligible enrollees and their providers.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to

comments, we are finalizing the provision as proposed with technical changes to reflect changes to regulation text made by the MOOP April 2022 final rule, CMS–4190–FC4. Specifically, in paragraphs § 422.100(f)(4) and (f)(5)(iii) and in paragraph § 422.101(d)(4), we are removing the word ''incurred'' and adding in its place the word ''accrued''.

13. Comment Solicitation on Coordination of Medicaid and MA Supplemental Benefits

Section 422.107 requires each MA organization offering a D–SNP to have a contract with the State Medicaid agency that describes, among other things, the organization's responsibility to coordinate Medicaid benefits. State Medicaid agencies have broad flexibility to include provisions in their D–SNP contracts.

In the proposed rule, we described a number of ways that State Medicaid agencies can use their D–SNP contracts under § 422.107 to coordinate D–SNP supplemental benefits with Medicaid benefits. The proposed rule described specific examples of potential coordination of MA supplemental benefits and Medicaid coverage, including Medicaid benefits that are delivered through Medicaid FFS, through a separate Medicaid managed care contract, or by the State capitating the D–SNP for delivery of these benefits. The examples demonstrated how this coordination can ensure the overlapping D–SNP supplemental benefits are primary to Medicaid, how to ensure D–SNPs and Medicaid providers do not receive duplicative payments for delivery of the identical benefits to the same individuals, how D–SNP supplemental benefits can extend or expand on similar Medicaid benefits, and how D–SNP enrollees can have a more integrated experience of care. The examples included discussion of typical D–SNP supplemental benefits, such as coverage of dental services and non-emergency transportation, as well as delivery of supports for community living. We described how CMS considers a FIDE SNP's supplemental benefits as meeting the uniformity requirements in cases where some dually eligible individuals receive the benefit under the FIDE SNP's Medicaid managed care contract while other enrollees receive the benefit as an MA supplemental benefit because they are not eligible for Medicaid benefits under State Medicaid eligibility criteria. We noted that we were considering whether an amendment to § 422.100(d)(2) would be appropriate regarding this approach to uniformity for supplemental benefits when a FIDE SNP arranges supplemental benefits this way and sought comments on that issue. We also solicited comment on other potential ways that D–SNPs and States can work together to coordinate Medicare and Medicaid benefits in order to improve D–SNP enrollee experiences and outcomes.

Comment: Several commenters supported the use of D–SNP contracts to coordinate MA supplemental benefits with Medicaid. A few commenters expressed concerns with operationalizing the coordination of supplemental benefits because of the complexity and limitations in data sharing and inadequate data systems. Other commenters recommended increasing information sharing to better integrate coordination of Medicare and Medicaid services. Several commenters also requested more oversight and data collection of supplemental benefits. A commenter believed that the use of D–SNPs to coordinate Medicare and Medicaid benefits would place much of the responsibility on the D–SNPs and would require expensive sophisticated integrated IT systems for the exchange of data. A few commenters raised concerns with enrollee access to services and enrollee confusion about D–SNP supplemental benefits when they overlap with Medicaid benefits.

Response: We appreciate the commenters' perspectives and thank the commenters for their input. These comments will inform our collaboration with States on D–SNP integration.

(a) Using the D–SNP MOC To Coordinate Medicaid Services

As described in the proposed rule, the D–SNP MOC, required by § 422.101(f), also provides a vehicle for State Medicaid agencies to work with D–SNPs to meet State goals to improve quality of care and address social determinants of health. State Medicaid agencies may work with D–SNPs with service areas in the State to include (and, through the State Medicaid agency contract at § 422.107, require inclusion of) specific elements in the MOC and how the D–SNP delivers covered items and services consistent with the MOC. There is no prohibition on a State Medicaid agency imposing specific requirements for the D–SNP MOC that are in addition to the minimum requirements at § 422.101(f); compliance with the approved MOC is included in the D–SNP's bid to provide basic benefits under § 422.101(f). For example, the State Medicaid agency contract under § 422.107 could require the D–SNP to have specific community-based providers involved in development of individualized care plans, deploy nurse practitioners for in-home care for high-risk enrollees when in-home services are required by the individualized care plans, use health care providers (rather than plan staff) for care coordination functions, and/or set minimum payment amounts for such providers. We solicited comments on CMS guidance or regulations that may warrant clarification, and whether using D–SNP MOC to coordinate Medicaid services create any unintended obstacles to accessing services among dually eligible beneficiaries.

Comment: A few commenters supported using the D–SNP MOC to coordinate Medicaid services and a commenter supported more transparency by incorporating the MOC process into the regulatory and contractual oversight regime. Several plan sponsors and their trade associations expressed concern with the State's ability to leverage the MOC with Medicaid requirements and the possible addition of any State requirements that may be duplicative or in conflict with the MOC-specific requirements. A few commenters suggested potential ways to improve coordination such as training for States on Federal requirements, a national State specific requirements repository, and better alignment of MOC reviews.

Response: We appreciate the commenters' support and will take into consideration the additional comment on enhancing transparency. We also thank the commenters for suggesting ways to improve MOC alignment with the State coordination process and will take these into consideration in future rulemaking and guidance.

(b) Coordinating Coverage of Medicare Cost-Sharing

As stated in the proposed rule (87 FR 1887), the same prohibition on duplicate Medicare and Medicaid payments for identical benefits applies when a D–SNP covers MA supplemental benefits that reduce Medicare Parts A and B cost-sharing, such as deductibles and coinsurance, as described for overlapping coverage of other Medicaid and MA supplemental benefits. How it works depends on whether the State Medicaid agency pays for Medicare cost-sharing through the Medicaid FFS program or pays the D–SNP a capitated amount to cover the State's obligation to pay MA cost-sharing. The proposed rule included examples (87 FR 1887) of both State payment arrangements for MA cost-sharing. We solicited comments on State and MA organization experiences and challenges in coordinating benefits, CMS guidance or regulations that may warrant clarification, and whether our current policies create any unintended

obstacles to accessing services among dually eligible beneficiaries.

Comment: A few commenters supported coordinating coverage of Medicare cost-sharing and noted that Medicaid capitation for coverage of Medicare cost-sharing will need to be projected accurately and actuarially sound.

Response: We thank commenters for raising this issue. We will consider opportunities for future Medicaid rate-setting guidance on the issue.

14. Solicitation of Comment on Converting MMPs to Integrated D–SNPs

In the 10 years since the creation of the FAI, the integrated care landscape has changed substantially. Congress made D–SNPs permanent in 2018 and established, beginning in 2021, new minimum integration standards and directed the establishment of unified appeals and grievance procedures (which we tested through the MMPs). Changes in MA policy have also created a level of benefit flexibility that did not previously exist outside of the capitated model demonstrations, with MA plans increasingly offering supplemental benefits that address social determinants of health and long-term services and supports.[71] These factors, in combination with the proposals discussed earlier in this final rule, offer the opportunity to implement integrated care at a much broader scale than existed when MMPs were first created. As a result, we described in the proposed rule at 87 FR 1888 our intent, contingent on finalizing other proposals in the rule, to work with the States participating in the capitated financial alignment model during CY 2022 to develop a plan for converting MMPs to integrated D–SNPs. Table 1 summarizes how our proposals finalized in this rule relate to MMP policies.

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TABLE 1: PROPOSALS FINALIZED IN THIS RULE THAT APPLY MMP FEATURES TO D-SNPs

MMP Characteristic	FIDE SNP	HIDE SNP	Coordination-only D-SNP
Enrollee advisory committee	Required	Same as FIDE	Same as FIDE
HRA to include social risk factors	Required	Same as FIDE	Same as FIDE
Exclusively aligned enrollment	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Capitation for LTSS and behavioral health	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Capitation for Medicare cost-sharing	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Unified appeals & grievances[1]	Required starting 2025 for all FIDE SNPs	Not addressed in this rulemaking	Required for certain plans
Continuation of Medicare benefits pending appeal[2]	Required starting 2025 for all FIDE SNPs	Not addressed in this rulemaking	Required for certain plans
Integrated member materials	Finalized a new pathway for States to require for certain plans	Same as FIDE	Same as FIDE
Contract only includes within-State plans limited to dually eligible individuals Quality data/ratings based solely on performance in contracts that only include within-State plans limited to dually eligible individuals[3]	Finalized a new pathway for States to require for certain plans	Same as FIDE	Same as FIDE
Mechanisms for joint Federal-State oversight	Finalized for States meeting specified criteria at § 422.107(e)	Same as FIDE	Same as FIDE
State HPMS access	Finalized for States meeting specified criteria at § 422.107(e)	Same as FIDE	Same as FIDE

NOTES: HPMS: Health Plan Management System; LTSS: long-term services and supports

[1]The requirement for unified appeals and grievances was already in place for those FIDE SNPs and HIDE SNPs that are applicable integrated plans, as defined at § 422.561. Our requirement for exclusively aligned enrollment for FIDE SNPs beginning 2025 means that all FIDE SNPs will be applicable integrated plans subject to the requirements for unified appeals and grievance systems. In addition, this final rule revises the definition of applicable integrated plans to extend requirements for unified appeals and grievance systems to a subset of coordination-only D-SNPs.

[2]The requirement for continuation of Medicare benefits pending appeal was previously adopted at § 422.632 for those FIDE SNPs and HIDE SNPs that are applicable integrated plans, as defined at § 422.561. Our requirement for exclusively aligned enrollment for FIDE SNPs beginning 2025 will mean that all FIDE SNPs will be applicable integrated plans subject to this requirement of a unified appeals system.

[3]CMS calculates Star Ratings at the contract level. Star Ratings will become specific to plans serving dually eligible individuals where the MA contract is limited to a one or more D-SNPs. We did not propose or finalize changes to require Star Ratings to be calculated at the plan level *per se*. (*See* §§ 422.160 through 422.166.)

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We described in the proposed rule at 87 FR 1888 the process for transitioning MMPs to D–SNPs and the potential advantages and disadvantages of such a transition. In order to mitigate any disruptions that could result from converting MMPs to D–SNPs, we intend to work closely with States and other stakeholders to ensure the transition is as seamless as possible for MMP enrollees, including facilitating the transition of MMP enrollees to D–SNPs

[71] ATI Advisory. *New, Non-Medical Supplemental Benefits in Medicare Advantage in 2021.* May 2021. *https://atiadvisory.com/wp-content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf.*

operated by the same parent organization, subject to State approval, unless enrollees choose otherwise. This could minimize disruption of services and ensure continuity of care to the greatest extent possible. As discussed in the proposed rule, we already have experience with similar transitions at the end of the Virginia [72] and New York MMP demonstrations [73] and are working closely with the California Department of Health Care Services and MMPs to facilitate such a transition when the Cal MediConnect demonstration concludes at the end of 2022.[74] We solicited comment on this contemplated approach to working with States to convert MMPs to integrated D–SNPs.

Comment: Several commenters expressed support for our approach to work with States to develop a plan for converting MMPs to integrated D–SNPs. A few commenters stated that this approach would simplify the number of products offered to dually eligible individuals and would be easier for States to administer and for beneficiaries and providers to understand while providing long-term predictability for stakeholders. Another commented that D–SNP models have been effective at managing hospitalizations and providing access to primary care and MLTSS services even without the promise of shared savings offered through MMPs.

Response: We appreciate the support we received for our intended approach. As discussed in the proposed rule, current law as well as the new and amended regulations finalized in this rule provide opportunities and potential for streamlining and strengthening integrated care options for dually eligible beneficiaries. We look forward to working with States to address their unique circumstances in planning for a transition of MMPs to integrated D–SNPs.

Comment: Numerous commenters opposed our approach to work with States to develop a plan for converting MMPs to integrated D–SNPs and instead asked to continue the FAI. Many commenters expressed concern that certain aspects of integrated coverage in the MMPs may be hard to replicate or are otherwise not currently available in integrated D–SNPs, including integrated enrollment processing in which enrollment and disenrollment functions are operationalized through State Medicaid agencies; the ability to passively enroll beneficiaries into integrated plans; integrated financing that blends Medicare and Medicaid capitation payments; and/or opportunities for States to share in Medicare savings. Several commenters recommended CMS provide additional guidance and opportunities for comment on how such a transition would work in States where D–SNPs are not offered or where certain benefits are carved out before making a final decision regarding the future of MMPs. A number of commenters, including States, plan sponsors, and advocates, expressed concern that ongoing funding for dedicated ombudsman and one-on-one options counseling services would be lost as part of the transition out of the FAI and urged CMS to continue support for these programs.

Response: We thank the commenters for the feedback on our intended approach for working with States. Several of the new and amended regulations adopted in this final rule create mechanisms and new requirements to replicate much of the programmatic or administrative integration found in MMPs including integrated member materials, unified appeals and grievances, continuation of Medicare benefits pending appeals, elements of joint CMS/state oversight, and contract-specific quality ratings. States can also use their State Medicaid agency contracts with D–SNPs, as described throughout this final rule, to establish parameters that promote person-centered and integrated care, including exclusively alignment enrollment, additional requirements for care planning and self-direction, and enrollment limited to certain age groups or other variables. Other aspects of integration tested in the FAI will not be possible under current law or the new and amended regulations adopted here, and we acknowledge commenters' concerns to that end. However, we believe that the ability to maintain most, if not all, aspects of integration outside the confines of time-limited demonstrations outweighs the potential loss in the identified areas. Although outside the scope of this rule, we will consider whether there are additional opportunities to further integrate enrollment and/or financing in the future.

We intend to work closely with States and other stakeholders not only to develop a transition plan that would allow States to preserve the integration currently available through MMPs to the greatest extent possible but also to provide subsequent technical assistance and resources to support these efforts, including in scenarios where States do not currently contract with D–SNPs or where certain benefits are carved out.

We agree with commenters that dedicated ombudsman and one-on-one options counseling services provide important beneficiary protections. Existing grant awards already include a transition period as part of the cooperative agreements currently in place, and we will work closely with States on potential sustainability plans. We note that Virginia, for example, was able to continue its ombudsman services at the end of its FAI demonstration without grant assistance.

Comment: We received numerous comments in support of the Massachusetts One Care demonstration. Several commenters expressed concern that the elements unique to this demonstration would not be applied to the D–SNP model of care or contracting requirements and, as a result, key attributes of the One Care model would be lost in such a transition. Several commenters highlighted the value the consumer-led Implementation Council provides in plan oversight and to ensure the demonstration retains its person-centric, independence-driven approach, and expressed concerns that the Council would be diminished or eliminated in an integrated D–SNP environment.

Response: We appreciate the ongoing support for the One Care demonstration. We look forward to working with the State and other stakeholders, including the Implementation Council, on how to sustain and strengthen the person-centric, independence approach for which One Care is known.

Comment: Numerous commenters, including States, plan sponsors, and advocates, urged CMS to take steps to ensure a smooth transition for enrollees if CMS moves forward with transitioning MMPs to integrated D–SNPs. Such steps included: Use of passive enrollment to transition MMP enrollees to corresponding D–SNPs; requiring continuity of care provisions to ensure stability of coverage and access to providers; and/or ongoing stakeholder engagement that includes

[72] Centers for Medicare & Medicaid Services and Virginia Department of Medical Assistance Services. *Commonwealth Coordinated Care (CCC) Phase-Out Plan. https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/VAPhaseOutPlan.pdf.*

[73] Centers for Medicare & Medicaid Services and New York Department of Health. *New York Fully Integrated Dual Advantage Demonstration Phase-Out Plan.* September 2019. *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYFIDAPhaseOutPlan.pdf.*

[74] California Department of Health Care Services. *Expanding Access to Integrated Care for Dual Eligible Californians.* March 2021. *https://www.dhcs.ca.gov/provgovpart/Documents/6422/Expanding-Access-to-Integrated-Care-for-Dual-Eligible-Californians-03–01–21.pdf.*

advocates, MMPs, and D–SNPs to promote collaborative discussion on the planning and implementation of integrated D–SNPs and ensure aligned messaging and coordination. Many commenters recommended that CMS provide technical assistance and resources for States on topics related to Medicaid managed care authorities, contracting options, and operational steps to assist with the transition from MMPs to D–SNPs. A few commenters strongly supported using 1115A authority to facilitate the transition of MMP enrollees to D–SNPs operated by the same parent organization, subject to State approval, unless enrollees choose otherwise.

Response: We appreciate the feedback on the necessary transition steps, and we agree that ensuring an MMP to D–SNP transition is as seamless as possible for MMP enrollees is critical to successfully implementing this approach. We continue to think through our ability to use waiver authority under section 1115A of the Act as part of any MMP transition. We are committed to working closely with States and other stakeholders and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center.

Comment: The majority of commenters on this section of the proposed rule, including States, advocates, and plan sponsors, stated that additional time would be needed beyond the current end date in order to allow sufficient runway for a seamless transition of operations and enrollment. Commenters made this statement regardless of whether or not they supported the overall approach. Most suggested at least two additional years would be needed for States to evaluate options and obtain necessary authorities, vet policy proposals with stakeholders, make necessary State system changes, and conduct procurements, if necessary, in order to ensure that MMP enrollees experience a seamless and easy transition from their MMP to a successor FIDE SNP or HIDE SNP.

Response: We thank the commenters for these comments. We acknowledge the commenters' concerns about the time necessary to ensure a seamless transition for all parties involved.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we intend to adjust our approach to working with the States participating in the capitated financial alignment model to develop a plan for converting MMPs under the FAI model test to integrated D–SNPs. We will offer States the opportunity to continue demonstrations under the FAI, under conditions described in this section and where authorized by section 1115A of the Act.

States interested in this opportunity will need to convert all MMPs to integrated D–SNPs as early as possible, but no later than December 31, 2025. This timeframe reflects the perspectives expressed in public comments related to the time needed for a smooth transition.

States pursuing converting their MMPs into integrated D–SNPs should submit a transition plan to CMS by October 1, 2022. This transition plan should reflect each State's individual circumstances and outline, for example, the State's commitment to (a) maximize integration attained through the capitated financial alignment demo and a seamless transition to integrated D–SNPs, (b) sustain dedicated ombudsman support without Federal grant funding, and (c) a stakeholder engagement process to promote collaborative discussion on the planning and implementation of the transition to integrated D–SNPs. The transition plan should also identify specific policy and/or operational steps that need to occur to fulfill the commitments. These could include, but are not limited to, executing Medicaid procurement and/or D–SNP contracting processes; obtaining necessary State legislative or additional Medicaid authorities, if applicable; and/or identifying and executing system changes and processes to implement exclusively aligned enrollment.

If a State chooses not to convert MMPs to integrated D–SNPs, CMS will work with the State on an appropriate MMP conclusion by December 31, 2023. In all cases, we look forward to working with States, beneficiaries, advocates, and other stakeholders to continue our work to improve outcomes and experiences for dually eligible individuals.

B. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

In the February 12, 2015, final rule titled ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (80 FR 7959) (hereinafter referred to as the 2015 final rule), CMS finalized a new paragraph (m) in § 422.100 to codify and clarify an MA organization's responsibilities when health plan services are affected by disasters or emergencies, including public health emergencies (PHEs), to ensure that MA enrollees continue to have access to care when normal business operations are disrupted and to ensure out-of-network providers are informed of the terms of payment for furnishing services to affected enrollees during disasters or emergencies. During the Coronavirus 2019 Disease (COVID–19) PHE, we have received questions about the applicability of the special requirements at § 422.100(m), which prompted us to review the regulation and the laws related to the declaration of disasters and emergencies. In light of this review, we proposed changes to clarify potential ambiguities in the regulation text, to further clarify the basis for determining the end of an MA organization's obligations to comply with special requirements during a disaster or emergency and codify our previous guidance in Chapter 4 of the Medicare Managed Care Manual (MMCM). Specifically, we proposed to revise § 422.100(m) to more clearly specify when MA organizations must begin ensuring access to covered benefits by meeting the requirements in paragraphs (m)(1)(i) through (iv) and when MA organizations are permitted to stop meeting those requirements.

Section 1852(d) of the Act requires MA organizations to provide continued availability of and access to covered benefits, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week; the ability to limit coverage to benefits received from a plan's network of providers is contingent on fulfilling this obligation. When a disaster or emergency occurs, enrollees may have trouble accessing services through network providers or sometimes must physically relocate to locations that are outside of their MA plan's service area. Currently, § 422.100(m) requires MA organizations to ensure access, at in-network cost-sharing, to covered services even when furnished by noncontracted providers when disruption in their MA plan's service area during a state of disaster or emergency impedes enrollees' ability to access covered healthcare services from contracted providers. Consistent with uniformity requirements for MA plans at § 422.100(d) and other regulations, these special requirements must be uniformly provided to similarly situated enrollees who are affected by the state of disaster or emergency.

First, we proposed to amend the regulation to explicitly limit the application of the special requirements to when there is a disruption in access to health care. In the 2015 final rule, we stated in the preamble that the regulations at § 422.100(m) were added to require MA organizations to ensure

access, at in-network cost-sharing, to covered services even when furnished by noncontracted providers ''when a disruption of care in the service area impedes enrollees' ability to access contracted providers and/or contracted providers' ability to provide needed services.'' (80 FR 7953) We proposed to revise § 422.100(m)(1) to include that there must also be a disruption of access to health care in addition to a disaster or emergency declaration for the MA organization to be required to ensure access to covered benefits consistent with the special requirements described in § 422.100(m)(1). We proposed to define ''disruption of access to health care'' for purposes of these special requirements by adding a new paragraph (m)(6); as proposed, a ''disruption of access to health care'' for the purpose of § 422.100(m) is an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a). The intent of these modifications is to clarify that if there is a current state of disaster or emergency that is not contributing to a disruption in health care services, then MA organizations would not be required to follow the requirements at § 422.100(m)(1)(i) through (iv). During a state of disaster or emergency, MA organizations must continue to meet MA access and availability requirements consistent with the normal prevailing community pattern of health care delivery in the areas where the network is being offered. During a state of disaster or emergency, disruptions caused by the disaster or emergency may prevent contracted providers from providing services to enrollees. If enough contracted providers are unavailable to enrollees, then the MA plan would not have enough contracted providers consistent with the normal prevailing community pattern of health care delivery in the service area. Per the proposed definition, this would indicate that there is a disruption in access to health care in the service area, and MA organizations would be required to follow the special requirements at § 422.100(m)(1). This definition is not intended to be limited to physical barriers to access (such as electrical outages or transportation difficulties caused by hurricanes or wildfires) but to be broad enough to encompass any interruption or interference caused by a disaster or emergency such as a lack of available hospital beds or quarantine restrictions. Therefore, under our proposal, when a disaster or emergency interrupts that level of access to and availability of services, MA organizations must ensure access by covering basic and supplemental benefits furnished at non-contracted facilities; waiving, in full, requirements for gatekeeper referrals where applicable; providing in-network cost-sharing even if the enrollee uses out-of-network providers; and making changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3). Limits in other regulations, such as §§ 422.204(b)(3) and 422.220 through 422.224, on which healthcare providers may furnish benefits remain in place and are not eliminated by § 422.100(m).

In the definition, we refer to the normal prevailing community pattern of health care delivery in the service area as it usually is when a state of disaster or emergency does not exist, not the prevailing community pattern of health care delivery in the service area during the state of disaster or emergency. During a state of disaster or emergency, it is possible that access to health care will be disrupted affecting more than MA enrollees, including access to care for enrollees in commercial plans and Original Medicare. To provide an extreme example, an MA organization could indicate that its MA plans are meeting the prevailing community pattern of health care delivery when all of the primary care providers in the service area are closed due to a state of disaster, and the MA plans are therefore meeting the standard because everyone in the service area, no matter the type of insurance they have, cannot access primary care providers. As explained above, this would not be acceptable, as CMS is measuring the prevailing community pattern of health care by reference to the pre-disaster period. Under the proposed regulation, MA organizations would be required to ensure access for their enrollees by complying with the special requirements listed at § 422.100(m)(1)(i) through (iv). While we consider the standard to be the normal prevailing community pattern of health care delivery, we understand this standard broadly in the context of disasters and emergencies. Some examples that would constitute a disruption in access to health care include physical barriers to accessing health care such as road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID–19 pandemic. This list is not intended to be exhaustive as many unforeseen circumstances may arise during states of disaster or emergencies that may cause enrollees to have trouble accessing services through normal channels or force them to move to safer locations that are outside of their plan's service areas. A disruption in access to health care could include disruptions in access to Medicare Part A or Part B services or to supplemental benefits offered by the plan, or any combination of those. Our proposal is intended to be broad and to focus on actual access to and availability of services for enrollees in a service area affected by a disaster or emergency. Whether the MA plan network continues to meet evaluation standards specified in § 422.116 is not the only relevant consideration. For example, regarding a hospital with beds or other equipment unavailable to treat additional patients (as has occurred during COVID–19 pandemic), the hospital remains part of the MA organization's network, and therefore the network may be consistent with CMS's network adequacy standards for MA plans, but enrollees would not be able to access the hospital and may need to go to out-of-network providers to access their covered benefits. Similarly, physical barriers that enrollees may experience during a disaster or emergency (road closures, flooding, etc.) may affect enrollees unevenly, preventing some enrollees from accessing in-network providers. The provider may be part of the MA organization's network and therefore the network may meet the time and distance evaluation standards in § 422.116 and appear to be capable of furnishing services consistent with the prevailing community pattern of health care, but some enrollees may experience difficulty accessing that provider to obtain needed health services. Further, if an enrollee had to leave their home to move to a different location due to a disaster or emergency, the MA organization may still have a network that meets the prevailing community pattern of health care in the service area of the enrollee's home, but the enrollee may not be able to access health care in their different location without being able to access out-of-network care. We requested comments from stakeholders on our proposed definition to determine whether there are circumstances CMS is

not considering or additional standards that we should be using to identify when a disruption of access to health care is occurring.

We proposed to add a disruption of access to health care as a condition that must be met before the special requirements in § 422.100(m)(1) apply in order to ensure that this regulation is not overly broad and is appropriately tailored to address our concerns that MA enrollees have adequate access to medically necessary care and are not unduly restricted to the MA plan's network of providers. As an illustrative example of a situation where a disruption of access to health care was not present even though a state of emergency was in effect, the Governor of Hawaii issued a state of emergency [75] to fight the Zika virus in February of 2016. This state of emergency did not require all MA organizations operating in Hawaii to comply with the requirements at § 422.100(m)(1) because all provider offices were operating as usual, contracted providers continued in their ability to provide needed services, and enrollees did not face barriers in accessing needed services. The Opioid PHE, which began in 2017, is another example where there is a declared PHE by the Secretary that has been ongoing, but it does not necessarily constitute a disruption of access to health care. However, in 2017, Hurricane Maria in Puerto Rico led to substantial issues with access to covered services for MA enrollees. In connection with the Hurricane Maria, there was a Presidential declaration of a major disaster under the Stafford Act on September 20, 2017 [76] and a Public Health Emergency declaration by the Secretary as of September 17, 2017.[77] Under our proposal, MA organizations would be required to meet the special requirements at § 422.100(m)(1) for the duration of similar disasters and emergencies where access to covered benefits is disrupted.

We proposed that MA organizations would be initially responsible for evaluating whether there is a disruption of access to health care under § 422.100(m). We believe MA organizations are best positioned to evaluate if a state of disaster or emergency is disrupting access to health care for enrollees in their service area. MA organizations would know the status of their in-network providers (for example, whether they are operational or not, how many beds are filled, etc.) and would be in communication with their providers as issues at the provider's facilities or with an MA organization's enrollees arise. MA organizations should be guided by the explanations here, including the examples, as well as their particular and detailed knowledge and understanding of their enrollees, service areas, and networks, to reasonably assess if there is a disruption in access to health care in the service area. CMS expects that MA organizations should be aware of these and other facts regarding access to health care in the service areas where they offer plans, and should be able to evaluate those facts and apply the standard in the regulation to know when they must comply with the special requirements at § 422.100(m). CMS will monitor access during disasters or emergencies to ensure MA organizations are applying the standard in § 422.100(m)(1) correctly and complying with this regulation to avoid any disruptions in access to care. As we monitor, we will evaluate whether and when the standard in § 422.100(m)(1) as proposed to be amended here is met. If CMS discovers that there are problems with access for enrollees, we will direct MA organizations in the affected area to comply with § 422.100(m). However, we reiterate that an MA organization should be able to apply the standard in the regulation to the relevant facts related to a potential disruption in access to care during a disaster or emergency and to know the regulatory standard with regard to disruption in access to care during a disaster or emergency and when compliance with the special requirements during a disaster or emergency at § 422.100(m) is required. MA organizations are required to meet the network adequacy requirements at §§ 422.112(a) and 422.116 at all times to ensure enrollees have sufficient access to covered benefits. MA organizations that fail to meet network adequacy requirements must ensure access to specialty care by permitting enrollees to see out-of-network specialists at the individual enrollee's in-network cost-sharing level under § 422.112(a)(3). In addition, MA organizations may need to make alternate arrangements if the network of primary care providers is not sufficient to ensure access to medically necessary care under § 422.112(a)(2). This proposal would not change these existing and continuing regulatory requirements.

Similar to what was experienced by MA enrollees during the COVID–19 PHE, CMS expects that there will be situations where disruptions are intermittent and access to health care is disrupted for some period of time during a disaster or emergency, but not at other times. Under our proposed regulation, MA organizations would follow the special requirements imposed by § 422.100(m)(1) for 30 days after the disruption of access to health care ends while the disaster or emergency is ongoing and for 30 days after the end of the disaster or emergency if the disruption of access to health care, as defined in § 422.100(m)(6), continues until the end of the disaster or emergency. MA organizations may also find that at a later time period, during the same declared disaster or emergency, there is another disruption of access to health care and therefore that the MA organization must again follow the special requirements imposed by § 422.100(m)(1). We also recognize that there may be circumstances when a state of disaster or emergency is declared for an area containing multiple service areas (for example, the entire United States), but the disaster or emergency may unequally affect the various service areas contained in the larger area for which it is declared. It may be that some service areas experience a disruption of access to health care, but other service areas do not, or that the disruption in care ends for certain service areas but continues in others. Under our proposed regulation, in situations where a disruption of access to health care ends in a particular service area, but the state of disaster or emergency continues to be in effect for an area that includes that particular service area, the special requirements imposed by § 422.100(m)(1) would be in effect for the service areas in which there is a disruption of access to health care (until 30 days after the disruption of access to health care ends) and would not be in effect for services in which there has not been any disruption of access to health care.

We also proposed two technical changes to our regulations at § 422.100(m)(2) to correct some numbering issues that occurred in the 2015 final rule. First, we proposed to move the text from the fourth-level paragraph at (m)(2)(ii)(A) to the third-level paragraph at (m)(2)(ii), which currently does not have text associated with it. As amended, the regulation at § 422.100(m)(2)(ii)(A) would state that the Secretary of Health and Human Services (hereinafter referred to as the Secretary) may declare a PHE under section 319 of the Public Health Service

[75] *https://governor.hawaii.gov/wp-content/uploads/2016/02/160212_EmergencyProclamation_Dengue.pdf.*

[76] *https://www.govinfo.gov/content/pkg/FR-2017-10-06/pdf/2017-21649.pdf.*

[77] *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Puerto-Rico-and-US-Virgin-Islands-PHE-Determination.pdf.*

Act. Second, we proposed to remove the fourth-level paragraph at (m)(2)(ii)(B) because this paragraph only provides information about the Secretary's section 1135 waiver authority which is not an authority under which the Secretary may declare PHEs. In addition to these technical changes, we proposed several clarifying revisions to our language in § 422.100(m) to ensure that we are consistently referring to disasters and emergencies. Currently, the language sometimes refers only to disasters (as in the introductory text to paragraphs (m)(1) and (2)), but also refers to disasters and public health emergencies (as in the text to paragraphs (m)(3) and (4) and (m)(5)(i)). We therefore proposed to update the language throughout to reference disasters and emergencies with the aim of being consistent in referring to the various types of declarations listed at § 422.100(m)(2).

Lastly, we proposed revisions to clarify the basis for determining when MA organizations are no longer required to comply with the special requirements for a disaster or emergency. We proposed to modify the text at § 422.100(m)(3) to clarify that it refers to the end of the special requirements for a state of disaster or emergency stipulated at § 422.100(m)(1), not to the end of the state of disaster or emergency itself. We also proposed to add a 30-day transition period to § 422.100(m)(3). Our current regulation at § 422.100(m)(3)(iii) provides a period of 30 days from the initial declaration for the special requirements imposed by § 422.100(m)(1) to be in effect if the initial declaration of the disaster or emergency does not contain a specific end date or if the official or authority that declared the disaster or emergency does not separately identify a specific end date, and CMS has not indicated an end date to the disaster or emergency. This means that, under the current regulation, there is usually a 30-day minimum period during which MA plans are providing access to covered benefits with the additional beneficiary protections specified in paragraphs (m)(1)(i) through (iv), unless an explicit announcement of the end of the disaster or emergency has been declared sooner than the end of the 30 days. We believe that having a minimum period for these protections is important and appropriate. A transitional period from when an MA organization must comply with the access requirements in § 422.100(m)(1) to when the MA organization must furnish services are required by normal coverage rules will protect enrollees who need time and assistance from the MA organization to find a contracted provider after having been treated by a non-contracted provider during the disaster or emergency. We intend for this period to serve as a protection for enrollees so they are not immediately responsible for the total cost of services received from a non-contracted provider that they have been seeing for a period of time due to the state of disaster or emergency. MA organizations may also find a transitional period helpful if they must contract with additional providers or otherwise make changes to their network to assist with their return to normal operations. We therefore proposed to revise the regulation text at § 422.100(m)(3) to require a 30-day transition period after the points in time identified in the regulation for the end of the special requirements. Specifically, we proposed to revise paragraph (m)(3) to provide that the applicability of the special requirements for a disaster or emergency in paragraphs (m)(1)(i) through (iv) end 30 days after the latest of the events specified in paragraph (m)(3)(i) or (ii) occur (that is, the latest end date in a case where there are multiple disasters/emergencies) or end 30 days after the condition specified in paragraph (m)(3)(iii) occurs (that is, there is no longer a disruption of access to health care).

In the 2015 final rule, we finalized three circumstances as determining the end of the special requirements for a disaster or PHE in the regulations at § 422.100(m)(3). First, as currently provided in § 422.100(m)(3)(i), the source that declared the disaster or PHE declares an end to it. As explained in § 422.100(m)(2), disasters or emergencies may be declared by the President of the United States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) or the National Emergencies Act, by the Secretary who may declare a PHE under section 319 of the Public Health Service Act, or by Governors of States or Protectorates. We intend paragraph (m)(3)(i) to address circumstances when the initial declaration contains a specific end date or when the official or authority who declared the disaster or emergency separately identifies a specific end date. We proposed to revise § 422.100(m)(3)(i) to address situations that may arise where there is more than one declaration of a disaster or emergency at the same time for the same service area(s). This proposed revision clarifies that MA organizations must follow the special requirements until the latest applicable end date when multiple declarations apply to the same geographic area by specifying that all sources that declared a disaster or emergency that include the service area have declared an end. For example, if a Governor of a State declares a state of disaster or emergency and the President also later declares a state of disaster, both the state and Federal disasters must be declared at an end to trigger § 422.100(m)(3)(i). If the President's disaster declaration ends after 20 days, but the Governor maintains the state of disaster for 30 days, then the special requirements imposed by § 422.100(m)(1) would apply for MA plans in that area through the end of the emergency declared by the Governor, plus an additional 30 days for the transition period we proposed.

Second, the regulation currently provides that CMS may declare an end to the state of disaster or PHE per § 422.100(m)(3)(ii). Upon review, we intended for this regulation text to refer to the Secretary's authority, which is consistent with the current practice of the Secretary to declare an end to PHEs. However, since the Secretary is already considered a source under § 422.100(m)(3)(i), we believe that modifying this requirement to refer to the Secretary is unnecessary and therefore we proposed to remove this text.

Third, our current regulation at § 422.100(m)(3)(iii) addresses circumstances where a state of disaster or PHE is declared with no end date identified. Because § 422.100(m)(3) provides that the end of the emergency or state of disaster ends when ''any'' of the three listed, if the declaration disaster or emergency timeframe has not been identified by the authority or official who declared the disaster or emergency and CMS has not indicated an end date to the disaster or emergency, MA plans should resume normal operations 30 days from the initial declaration. However, this does not properly account for how declarations of disasters or emergencies may be renewed with continued disruptions to access to health care services for enrollees. Further, our experiences with declarations of disasters and emergencies have demonstrated that the 30-day timeframe for the special requirements in § 422.100(m)(1)(i) through (iv) may not be enough time to address concerns about enrollees being able to access benefits during disasters or emergencies, especially in cases where a disaster or emergency declaration has been renewed. There are circumstances where a 30-day time period does not cover the full length of a declared

disaster or emergency and the current regulation is not well suited to ensure access for enrollees during the entire period of a disaster or emergency. For example, a PHE declared by the Secretary under section 319 of the Public Health Service Act is in effect for 90 days unless the Secretary terminates it earlier, and the Secretary may renew the declaration at the end of the 90-day period.

We proposed to revise § 422.100(m)(3)(ii) to address when no end date is identified under § 422.100(m)(3)(i); in such cases, the applicability of the special requirements ends 30 days after the expiration of the declared disaster or emergency and any deadline for renewing the state of disaster or emergency. This modification clarifies that when a state of disaster or emergency is declared without an end date, § 422.100(m)(1) will continue to apply for the entire duration of the declared disaster or emergency, as determined under the relevant authority under which it was declared, if a disruption of access to health care continues. Stafford Act declarations do not have a defined end date. When the President declares a national emergency under the National Emergencies Act, the declaration of a national emergency lasts for a year unless terminated earlier by the Presidential proclamation or a joint resolution of Congress. The President can renew the declaration for subsequent one-year periods. When the Secretary declares a PHE under section 319 of the Public Health Service Act, it lasts for 90 days unless the Secretary terminates it earlier, and it can be renewed for 90-day periods. For example, if the Secretary declared a PHE under section 319 of the Public Health Service Act, then the end date of the PHE would be in 90 days, unless renewed. If the Secretary chose to declare an end before the 90-day period ended, then the public health emergency would end according to the declared end date. CMS does not have the expertise to know whether all state declarations of emergency have a defined end date. Therefore, we did not propose specific time periods but proposed to amend § 422.100(m)(3)(ii) to account for extensions or renewals of declarations of the type identified in paragraph (m)(2).

Lastly, we proposed to add the disruption of access to health care as a limitation under revised § 422.100(m)(3)(iii) to indicate that the special requirements associated with a state of disaster or emergency may end when the disruption of access to health care ends, even if one of the circumstances in § 422.100(m)(3)(i) or (ii) to end the state of disaster or emergency has not yet occurred.

We intend to continue to issue sub-regulatory guidance as appropriate for MA organizations to explain how § 422.100(m) works, both through the HPMS system and through the CMS Current Emergencies web page at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies.-page*. Further, we note that the Secretary may exercise the waiver authority under section 1135 of the Social Security Act during an emergency period (defined in section 1135(g) of the Act), which exists when the President declares a disaster or emergency pursuant to the National Emergencies Act or the Stafford Act, and the Secretary declares a PHE pursuant to section 319 of the Public Health Service Act. Under the Secretary's section 1135 waiver authority, CMS may authorize DME and A/B Medicare Administrative Contractors (MACs) to pay for Part C-covered services furnished to MA enrollees and seek reimbursement from MA organizations for those health care services, retrospectively. Detailed guidance and requirements for MA organizations under the section 1135 waiver, including timeframes associated with those requirements and responsibilities, would be posted on the Department of Health and Human Services website, (*https://www.hhs.gov/*) and the CMS website (*https://www.cms.hhs.gov/*). MA organizations are expected to check these sites frequently during such disasters and emergencies.

We proposed the following changes to our regulations at § 422.100(m):

- Revise § 422.100(m)(1) to state that when a disaster or emergency is declared as described in § 422.100(m)(2) and there is disruption of access to health care as described in § 422.100(m)(6), an MA organization offering an MA plan must, until one of the conditions described in § 422.100(m)(3) of this section occurs, ensure access to benefits as described in § 422.100(m)(1)(i) through (iv).
- Revise § 422.100(m)(2) to refer to emergencies and disasters.
- Move the current text of § 422.100(m)(2)(ii)(A) to § 422.100(m)(2)(ii).
- Remove § 422.100(m)(2)(ii)(B).
- Revise § 422.100(m)(3) to specify that it addresses the end of the applicability of the special requirements rather than the end of the disaster or emergency.
- Revise § 422.100(m)(3) to add a transition period of 30 days after the earlier of the conditions described in § 422.100(m)(3)(i) and (ii) occurs or after the condition described in § 422.100(m)(3)(iii) occurs; during the transition, MA organizations must continue to comply with § 422.100(m)(1).
- Revise § 422.100(m)(3)(i) to clarify that MA organizations must follow the special requirements until all of the sources that declared a disaster or emergency in the service area declare it ended.
- Revise § 422.100(m)(3)(ii) to state that no end date was identified in § 422.100(m)(3)(i) of this section, and all applicable disasters or emergencies have ended, including through expiration of the declaration or any renewal of such declaration.
- Revise § 422.100(m)(3)(iii) to state that the special requirements identified in § 422.100(m)(1) of this section may also end if the disruption in access to health care services ends.
- Revise § 422.100(m)(4) to refer to disasters and emergencies.
- Revise § 422.100(m)(5)(i) to refer to disasters and emergencies.
- Add a new paragraph at § 422.100(m)(6) to define ''disruption of access to health care'' as an interruption or interference throughout the service area such that enrollees do not have ability to access contracted providers or contracted providers do not have the ability to provide needed services, resulting in MA organizations failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

We thank commenters for helping inform Special Requirements during a Disaster or Emergency. We received approximately 35 comments on this proposal; we summarize them and our responses follow:

Comment: Comments were very supportive of our proposal that there must also be a disruption of access to health care in addition to a declared disaster or emergency for special requirements during a disaster or emergency to apply.

Response: CMS thanks comments for their feedback.

Comment: Some commenters agreed that MA plans are in the best position to determine when there is a disruption in care and supported our proposal. Many of these commenters requested CMS release further guidance providing additional examples and objective criteria for MAOs to use in further determining ''disruption of access to care.''

Response: We thank commenters for their feedback. We proposed that a ''disruption of access to health care'' for the purpose of § 422.100(m) mean an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a). We are finalizing this definition with a slight change to provide that a disruption of access to health care occurs when the interruption or interference in access to health care occurs ''in'' the service area such that the standard we proposed is met. This revision is to be more consistent with our intent and discussion in the proposed rule that a disruption of access to health care may be targeted or specific to a limited area. Service areas are generally a county or larger and while many disruptions of access to health care may be county-wide or cover multiple counties, not all emergencies or disasters will result in such scope. Specific disruptions, such as those involving physical access (such as road damage or flooding that block access to or damage a hospital or larger provider group serving many enrollees) or damage to electrical supply or utilities, may be more limited in scope. So long as interruption or interference in access to health care in the service area is such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a) during a declared emergency or disaster as described in § 422.100(m)(2), it does not matter if that interruption or interference is limited to a specific area. In addition, we are clarifying in the regulation text that the term ''service area'' has the meaning provided in § 422.2.

Under this final rule, MA organizations must interpret and apply this regulatory standard (for when the special coverage requirements in § 422.100(m)(1) apply) by the explanations in the proposed rule and this final rule, including the examples, as well as their particular and detailed knowledge and understanding of their enrollees, service areas, and networks. Applications of § 422.100(m) are to be based on reasonable assessments whether and when there is a disruption in access to health care in the service area for enrollees in an MA plan. MA organizations must take into account available information regarding access to health care in the service areas where they offer MA plans and must reasonably evaluate those facts and apply the standard in the regulation to know when they must comply with the special requirements at § 422.100(m). CMS will similarly be guided by the same things when evaluating MA organization compliance with § 422.100(m) and when issuing instructions if CMS has determined that a disruption of access to health care has occurred in an area where a declaration of disaster or emergency has been made as described in § 422.100(m)(2).

As previously stated in this final rule, per § 422.112(a), MA plans must ensure that all covered services are available and accessible to enrollees under the plan. Additionally, we note CMS quantifies the prevailing patterns of care standard in network adequacy with the specific time and distance and minimum number of provider requirements at § 422.116. Per CMS regulations at § 422.112, MA plans are currently required to maintain and monitor a network of appropriate providers, supported by written arrangements, that is sufficient to provide adequate access to covered services to meet the needs of the population served. The delivery of services in particular geographic areas must be consistent with local community patterns of care. Simply put, MA plans must currently ensure that contracted providers are distributed so that no enrollee residing in the service area must travel an unreasonable distance to obtain covered services. Given that MA plans must already follow and monitor these existing requirements, we believe that MA organizations are in the best position to determine when and whether access to network providers has been compromised. We also encourage plans to look at how they ensure compliance with current access requirements when determining whether and when access to health care services has been disrupted.

Finally, to provide greater clarity, we are changing the term ''throughout the service area'' to ''in the service area'' at in the regulation text at § 422.100(m)(6). If the service area is several counties or an entire state but the natural disaster is limited to one county, ''throughout the service area'' could be interpreted to signify that there has not been a disruption sufficient to trigger § 422.100(m) if only one county is affected. That is not our intention. As discussed in the proposed rule, some examples that would constitute a disruption in access to health care include physical barriers to accessing health care such as road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID–19 pandemic. Any disruption of service within a given service area, whether it is multiple counties or one county, is sufficient to trigger the requirements at § 422.100(m). MA plans must follow 422.100(m) for all impacted enrollees. Additionally, we added a reference to the statutory definition of ''service area'' to provide further clarity on what CMS means by service area. Specifically, we define ''service area'' as it is defined at 42 CFR 422.2: a geographic area that for local MA plans is a county or multiple county, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization.

Comment: Some commenters expressed concern that allowing plans to determine whether there is a disruption in care may not sufficiently guarantee beneficiary protections. A few expressed concern that allowing each plan to make their own determination may lead to inconsistency (for example, different determinations by different plans) and confusion among enrollees. Others expressed concern that providers and MA plans in the same service area may disagree and asked CMS for clarification if these scenarios were to occur. Some commenters expressed concern that MA plans may have financial incentive to not apply or delay compliance with these special requirements.

Response: We thank commenters for expressing their concern. We reiterate that MA plans must provide enrollees health care services through a contracted network of providers that is consistent with the prevailing community pattern of health care delivery in the network service area (42 CFR 422.112(a)). Further, we note that that MA plans must meet current network adequacy requirements as defined under 42 CFR 422.116. Per § 422.112(a)(1), CMS requires that organizations monitor their contracted networks throughout the respective contract year to ensure compliance with the current network adequacy criteria. Given that plans are already required to ensure adequate access, we believe that

plans are best equipped to determine whether these existing standards have been compromised in a given service area or not.

Additionally, MA organizations must consider the extent to which services are accessible in the network (meaning, from network providers) and whether that access is consistent with normal community patterns of health care delivery and with access during periods when there is no declaration of disaster or emergency in effect. For example, if a plan has a sufficient network per CMS requirements, but enrollees are not able to access those contracted providers or those providers are unavailable or otherwise unable to furnish services to enrollees, this would be a disruption in access. As stated in the proposed rule, some examples of a disruption in access to health care include physical barriers to accessing health care providers, road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID–19 pandemic. A disruption of access has occurred if the existing network adequacy requirements and requirements for access to and availability of services cannot be met and/or enrollees cannot access the providers in this network. Given that plans are already required to monitor adequate access as discussed above, we believe MA plans are already in a position to determine if a disaster or emergency has compromised or disrupted normal patterns of access to, availability of, and delivery of covered services when those services are medically necessary. We encourage plans to evaluate whether an emergency or disaster has compromised their ability to meet these existing requirements when determining whether a disruption of access to health care as defined in § 422.100(m)(6) is occurring for purposes of meeting the special requirements in § 422.100(m).

Comment: A commenter suggested CMS change the 30-day transition period to one full month for additional clarity and to better align with plans' claims processing systems. Some suggested CMS extend the 30-day transition period, suggesting that 30 days may not be sufficient for enrollees to find new or alternative care. A commenter suggested 60 days instead of 30 days.

Response: We thank commenters for their feedback. Under our current regulations there is no explicit transition period but the general minimum period of time when an MA organization must comply with the special requirements in § 422.100(m)(1) is 30 days, and we believe that 30 days is sufficient in establishing how long an MA plan must continue to provide access to services as described in § 422.100(m)(1) after the end of an emergency or disaster period or end of a disruption of access to health care. However, we will consider revising this duration in future rulemaking if we determine that it is necessary. We note that MA organizations that find it more operationally feasible to maintain compliance with the special requirements in § 422.100(m)(1)(i) through (iv) for a full month or until the end of a month when that it is longer than the 30 days transition period are free to do so. As proposed and finalized, the 30-day transition period is the minimum requirement.

Comment: A commenter asked CMS to clarify how to determine the end point from which to begin calculating the 30 days transitional period.

Response: As stated in the proposed rule, MA plans are required to continue to apply special requirements for 30 days (the 30-day transitional period) after the points in time identified in the regulation at § 422.100(m)(3) for the end of the special requirements. For example, if the only applicable declaration of a public health emergency expires without renewal on April 30, the 30-day transition period ends on May 30 of the same year. If an MA organization reasonably determines, consistent with the regulation as it is adopted and explained in this final rule, that a disruption of access to health care has ended on January 1, the 30-day transition period will end on January 31.

Comment: Many commenters supported CMS's intention to continue to issue sub- regulatory guidance to further explain § 422.100(m) as appropriate and requested that CMS release guidance regarding events that might trigger special requirements and timeframes associated with those requirements.

Response: We thank commenters for their comments and plan to release additional sub-regulatory guidance on this subject as appropriate and as needed in the future.

Comments: We received some comments asking CMS to ensure transparency to providers and beneficiaries when these special requirements are put into place.

Response: We thank commenters for their concern. We remind MA plans that in addition to annual disclosure requirements at § 422.111, plans must follow emergency and disaster disclosure requirements at § 422.100(m)(5), which include indicating the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, annually notifying enrollees of information on the coverage requirements related to declarations of emergencies and disasters and providing this information on plan websites. Additionally, per CMS regulations at §§ 422.111 and 422.202(b), MA plans must establish policies and procedures to educate and fully inform contracted health care provider and, as appropriate, to enrollees concerning plan utilization policies, which should include any necessary information related to emergencies and disasters. We reiterate that we believe that MA organizations are generally in the best position to determine when and whether access to network providers in a service area has been compromised, so they will be expected to initiate compliance with § 422.100(m) as necessary and appropriate. We believe that the disaster disclosure requirements at § 422.100(m)(5) and general provider disclosure requirements at § 422.202(b) provide adequate transparency.

Comment: A commenter expressed concern that the special requirements will increase plan costs, noting that out of network coverage for an extended period is not included in plan rates. Another commenter requested OACT provide guidance on whether MA plans should include actuarial assumptions related to disaster and emergency events when developing prices for their contract year bids.

Response: We thank commenters for their feedback. When pricing a bid, the actuary should refer to the Actuarial Standards of Practice (ASOP). For example, ASOP No. 5 *Incurred Health and Disability Claims* says that when estimating incurred claims, the actuary should consider items such as changes in price levels, unemployment levels, medical practice, managed care contracts, cost shifting, provider fee schedule changes, medical procedures, epidemics or catastrophic events, and elective claims processed in recessionary periods or prior to contract termination (section 3.2.2 ECONOMIC AND OTHER EXTERNAL INFLUENCES).

Comment: A few commenters asked CMS to clarify whether special requirements should apply in other situations beyond national or state

emergencies, such as shortage of health care staff or other scenarios that may still impact normal patterns of community health care delivery.

Response: We thank commenters for their feedback. Section 422.112 requires MA plans to provide continued availability of and access to covered benefits for enrollees, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week. Additionally, § 422.113 provides that urgently needed services must be provided when an enrollee is temporarily absent from the plan's service (or, if applicable, continuation) area and therefore cannot obtain the needed service from a network provider and/or when the enrollee is in the service or continuation area but the network is temporarily unavailable or inaccessible. CMS has issued guidance about these requirements in section 20.2 of Chapter 4 of the Medical Managed Care Manual (MMCM). Further, per CMS regulations at § 422.112(a)(3), MA plans are required to arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Finally, MA plans are also currently required to meet network adequacy requirements at § 422.116(a)(2) all year, regardless if there is a declared state of emergency or not. Given these existing standards, we do not believe the special requirements discussed in this rule are necessary to apply outside of an emergency or disaster.

Comment: A commenter asked for more information on who has the authority to declare a state of disaster/emergency where these special requirements would apply. Another commenter asked CMS to remind state governors of their authority under 42 CFR 422.100(m). Another commenter stated that CMS should consider the state's role in determining when determinations the special requirements apply.

Response: The relevant types of disasters and emergencies are discussed in the proposed rule and reflected in § 422.100(m)(2) and include: (i) A Presidential declaration of a disaster or emergency under either the Stafford Act or the National Emergencies Act, (ii) a Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act, and (iii) a declaration by the Governor of a State or Protectorate. To further clarify, the special requirements discussed here do not impose any requirements on state governors. Rather, MA organizations are responsible for being aware of events discussed here, including an emergency or disaster declared by a Governor, in a given service area and knowing the status of their in-network providers and to applying requirements accordingly. We encourage MA plans to liaison with local and state authorities as appropriate when making a determination.

Comment: A commenter asked CMS to clarify whether waiving of ''gatekeeper'' referrals described at § 422.100(m)(1)(ii) includes the waiving of prior authorization (PA) in hospital discharges to other settings. Another commenter suggested CMS extend the requirements at § 422.100(m) to include waiving prior authorization for hospitals and post-care settings in general.

Response: As discussed in Chapter 4 of the MCM, the primary purpose of a gatekeeper is to ensure compliance with plan requirements for medically necessary referrals to in-network specialists. Under special requirements during an emergency or disaster, MA plans must cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities. Thus, such referrals are not applicable and must be waived during a qualifying disaster or emergency as described in this provision. We do not believe that adding a requirement that MA organizations waive prior authorization for hospitals and post-care settings at § 422.100(m)(1) is within the scope of our proposal to clarify and revise the time frame during which § 422.100(m)(1)(i) through (iv) apply. MA plans are permitted and encouraged to waive or relax plan prior authorization requirements at any time during disasters or emergencies in order to facilitate access to services and alleviate burden on enrollees, plans, and providers.

Comment: A commenter asked CMS to release guidance to address the needs of individuals who are required to evacuate from a disaster area, particularly those whose homes are damaged or destroyed in the disaster. Another commenter asked CMS to consider the special needs of the ESRD population.

Response: The emergency requirements at § 422.100(m) currently address coverage for people who have been evacuated or who had to move temporarily as a result of a disaster or emergency declaration by requiring plans to cover Parts A and B services and supplemental Part C benefits out-of-network. Also, § 422.100(b)(1)(iv) requires coverage of renal dialysis services provided while the enrollee was temporarily outside the plan's service area. Further, there is a Special Enrollment Period (SEP) for people who move out of the service area permanently. Thus, enrollees who cannot move back to the area of the disaster or emergency are permitted to change plans.

Additionally, we remind commenters that § 422.112(b) requires MA plans to ensure continuity of care and integration of services for enrollees through arrangements with contracted providers. Requirements in § 422.112(b)(1) through (6) detail specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. This includes requiring MA plans to have policies and procedures that provide enrollees with an ongoing source of primary care and to have programs for coordination of plan services with community and social services.

Comment: A commenter asked CMS to clarify the rate a non-contracted provider must be paid.

Response: As discussed in section 1852(a)(2) of the Act, CMS regulations at § 422.100(b)(2), and the MA Payment Guide for Out of Network Payments,[78] MA plans must pay non-contracted providers the amount that the provider would have received from Original Medicare amount for covered services (including balance billing permitted under Medicare Part A and Part B). The total payment must take into account cost-sharing and the MA plan payment to equal cost-sharing and Medicare payment in the Original Medicare program.

Comment: A few commenters suggested CMS align criteria related to special emergency requirements with the conditions for the Star Rating Extreme and Uncontrollable Circumstances adjustment.

Response: We thank commenters for their suggestion and will consider ways to align CMS policies if and when appropriate in the future.

Comment: A few commenters asked CMS to consider staffing, drug, and supply shortage issues to identify when a disruption of access to health care is occurring and when making decisions on timeframes and standards.

Response: We thank commenters for these suggestions and remind MA plans to also consider these conditions when making a determination whether a disruption of access to health care has occurred. The definition we proposed and are adopted in this final rule permits consideration of these conditions and factors when determining whether there is a

[78] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.*

disruption in access. Therefore, we believe that further edits to the proposed regulation text § 422.100(m)(6) is unnecessary.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are changing the term ''throughout the service area'' to ''in the service area'' at in the regulation text at § 422.100(m)(6). Also, to provide further clarity on what CMS means by service area, we added a reference to the statutory definition of ''service area'' in parenthesis at § 422.100(m)(6). Lastly, we edited some repetitive language at § 422.100(m)(1). Specifically, we revised ''until one of the conditions described in paragraph (m)(3)'' to ''until the end date specified in paragraph (m)(3) of this section occurs'', which is a non-substantive, clarifying edit only. We are finalizing all other changes proposed to § 422.100(m) without modification.

C. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

In the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS added new § 422.116, which sets forth standards and criteria for determining, whether an MA organization limits the providers from which its MA plan members may receive covered benefits, and satisfies the requirement under section 1852(d)(1) of the Act that such benefits be made available and accessible in an MA plan's service area with reasonable promptness.[79] New § 422.116 codified, with some modifications, network adequacy criteria and access standards that CMS had previously outlined in sub-regulatory guidance. In addition, the regulation codified our then-existing policy, that CMS does not deny an application based on CMS's evaluation of the applicant's network for a new or expanding service area. Under our policy as set forth in the June 2020 final rule and § 422.116(a)(2), an applicant is required to attest that it has an adequate network for access and availability of applicable provider and facility types at the time of the application for a new or expanding service area.

In the proposed rule (87 FR 1893 through 1895), we proposed to require compliance with applicable network adequacy standards set forth in § 422.116 as part of an application for a new or expanding service area. As indicated in the June 2020 final rule, we currently rely on our existing triennial network review process and timeline to evaluate compliance with network adequacy standards for organizations applying for a new or expanding service area and we removed network adequacy reviews from the application process beginning in 2018 for contract year 2019. We explained in the proposed rule that while the process of reviewing provider networks as part of the triennial review has thus far been adequate and efficient operationally, we have also experienced unintended consequences, and therefore proposed to improve our oversight and effectiveness of network adequacy reviews for initial and services area expansion (SAE) applicants by requiring provider networks be reviewed by CMS when these MA applications are submitted to CMS for consideration.

Currently, consistent with § 422.116(a)(1)(i) and our application process, applicants must attest that they meet provider network standards, but do not have to demonstrate that they meet CMS network requirements before submitting a bid for the following contract year. CMS's experience has shown that since adopting the attestation-only approach for the 2019 contract year, organizations are requesting to remove a county (or multiple counties) from their service area (that is, service area reduction) after bids are submitted because the organization realizes that it does not have a sufficient network for the entire service area. For example, five organizations have requested to make changes to the service area of a total of 10 plans after bid submission deadlines since 2019.

Bid integrity is a priority for CMS. A request by an organization to make service area reductions related to provider networks after the bid submission deadline, calls into question the completeness and accuracy of the bid(s). The provider network is an important consideration in preparing the bid submission. Permitting the MA organization to make changes to the bid submission because of the inability to establish an adequate network, which is reviewed after the first Monday in June (the bid deadline), would subsequently allow the MA organization to introduce revised information into the bidding process. The introduction of this revised information after the first Monday in June implies that the initial bid submission was not complete, timely, or accurate. The proposed requirement that MA networks be submitted for review as part of the application mitigates this issue, as CMS's review of these networks as part of the application is complete before bids are due.

Furthermore, network adequacy reviews are a critical component for confirming that access to care is available for enrollees. Our network evaluations ensure that MA organizations have networks that are sufficient to provide enrollees with access to providers and facilities without placing undue burden on enrollees seeking covered services. We indicated that adding network reviews back to the application process will help ensure overall bid integrity, result in improved product offerings, and protect beneficiaries.

After we adopted the current policy, failures detected during network reviews were not a basis for CMS to deny an application and CMS expected plans to cure deficiencies and meet network adequacy standards once coverage began on January 1 of the following year. In analyzing the network adequacy review determinations for the years since we removed network adequacy requirements from the application, we have observed a pattern across these network review outcomes: Organizations continue to have failures in their networks even after the contract is operational. For example, we found that 19 initial applicants who submitted provider and facility Health Service Delivery (HSD) tables since contract year 2019 continued to have deficiencies upon review of their networks once the MA plans were operational. We explained that by changing the process and reviewing the provider networks as part of the application, CMS will be able to better understand whether the failures are due to the timing of the reviews, which we hope the 10-percentage point credit (discussed later in this section of this final rule) will account for, or whether they are failures that the organization cannot cure. Establishing and maintaining adequate provider networks capable of providing medically necessary covered services to enrollees is fundamental to participation in the MA program.

Our current process and § 422.116(a)(1)(i) do not prohibit us, when evaluating an application, from considering information related to an organization's previous failure to comply with an MA contract due to previous failures associated with access to services or network adequacy

[79] As noted in the proposed rule at 87 FR 1893, CMS has also codified network access requirements and standards at §§ 422.112(a) and 422.114(a)(1).

evaluations resulting in intermediate sanction or civil money penalty under to part 422, subpart O, with the exception of a sanction imposed under § 422.752(d). This will continue to be applicable to our evaluation of initial or SAE applications. The changes we proposed, which require compliance with network adequacy standards during the application process, will help us assess which organizations are not capable of meeting CMS standards in a given service area. As a result, we proposed to broaden our ability to safeguard the MA program by permitting evaluations of network adequacy in connection with our review and approval of applications for new and expanding service areas. This ability will help us avoid approving organizations that could have issues providing access to care in these new or expanded service areas.

We found that the current timing of the network adequacy reviews impacts applicants' ability to make timely decisions regarding the service area in which they intend to provide coverage. The operational process for conducting network adequacy reviews is outlined in the ''Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance''.[80] The guidance currently directs initial and SAE applicants to upload their HSD tables containing pending service areas into the Health Plan Management System (HPMS) Network Management Module (NMM) in mid-June for CMS review. Regulations under § 422.254(a)(1) require organizations to submit bids no later than the first Monday in June of each year and authorize CMS to impose sanctions or choose not to renew an existing contract if the bid is not complete, timely and accurate. CMS has issued guidance to remind MA organizations of this obligation that bids be complete and accurate at the time of submission, such as in the CY 2014 through CY 2020 Final Call Letters (provided as attachments to the annual Rate Announcements [81]) and the CY 2022 MA Technical Instructions, released in an HPMS memo on May 12, 2021. Providing organizations with network adequacy determinations ahead of the bid deadline (within the application timeline) will provide them the opportunity to make decisions regarding their intended service areas before submitting bids. This practice would also help mitigate operational issues CMS has experienced related to requests for service area changes after the deadline has passed, as these kinds of requests may affect the MA organization's submissions on the bid pricing tool. For these reasons, we are finalizing our proposal to revise paragraph (a)(1)(ii) of § 422.116 to require an applicant for a new or expanding service area to demonstrate compliance with § 422.116 and to explicitly authorize CMS to deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

We also proposed to amend § 422.116 by adding a new paragraph (d)(7), which provide applicants with a temporary 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for all of the combinations of county designations and provider/facility types specified in § 422.116(d), for the proposed contracted network for a new service area or a service area expansion (SAE). Current CMS procedures (see ''The Part C—Medicare Advantage and 1876 Cost Plan Expansion and 1876 Cost Plan Expansion Application'' [82]) require completed applications to be submitted by mid-February. We understand that organizations may have difficulties meeting this timing for submission of a full provider network that the proposed change in § 422.116(a)(1)(i) would require. We previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational. In order to provide flexibility to organizations as they build their provider networks, we proposed to allow the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. At the beginning of the applicable contract year (that is, January 1), the 10-percentage point credit would no longer apply, and plans would need to be in full compliance for the entire service area. This aspect of our proposal will balance the burden on applicants of having network contracts in place close to a year before the beginning of the coverage year with the need to ensure that the MA plans have adequate networks for furnishing covered benefits to their enrollees.

Starting with the contract year 2024 application cycle, initial and service area expansion applicants will be required to submit their proposed contracted networks during the application process. Applicants will upload their HSD tables to the NMM by the application deadline, and CMS will generally follow the current operational processes for network reviews, which include an opportunity to submit exception requests as outlined in § 422.116(f). The disposition of the exception request would be communicated as part of the opportunity to remedy defects found in the application under § 422.502(c)(2). Applicants for SAEs who are also due for a triennial review would be required to submit their pending new service area during the application process, and their existing network service area(s) separately, during the triennial review in mid-June.

We acknowledge and thank commenters for providing their perspectives regarding our proposals to amend our network adequacy policy. We received a number of comments related to these proposals, and have summarized them and included our responses.

Comment: Numerous commenters expressed support for our proposal to require compliance with network adequacy standards as part of an application for a new or expanding service area. Commenters agreed that network adequacy is critical to enrollees' access to care. Commenters noted that improving our oversight of provider networks would strengthen beneficiary protections and ensure timely access to providers without placing undue burden on enrollees. Other commenters also noted that our proposal would hold plans accountable for providing access to care, especially in underserved communities.

Response: We thank the commenters for their support of our proposal. As previously noted, we believe that requiring MA organizations to demonstrate compliance with network adequacy standards during the application process for a new or expanding service area will improve our oversight and effectiveness of network adequacy reviews and our ability to safeguard the Medicare program.

Comment: Some commenters expressed support for our proposal to require that applicants demonstrate compliance with network adequacy standards during the application process because they believed this would help ensure bid integrity, which

[80] *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

[81] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[82] *https://www.cms.gov/files/document/cy-2022-medicare-part-c-application-updated-1-12-2021.pdf.*

the commenters agreed should be a priority for CMS.

Response: We thank the commenters for their comments regarding bid integrity. As indicated in our proposal, we believe that providing MA organizations with information regarding their ability to provide coverage in a proposed service area ahead of the bid deadline would mitigate issues with service area reduction requests and ensure overall bid integrity.

Comment: A commenter suggested that requests to make service area reductions after the bid deadline are relatively rare based on the number of new and service area expansion applications that are submitted, thus our proposal would needlessly increase burden on the entire industry for few occurrences.

Response: While there may be fewer instances of service area reduction requests relative to MA applications submitted, we believe that any such request has the potential to compromise the overall integrity of the bidding process. As we have previously indicated, ensuring overall bid integrity is a priority for CMS. In addition, we note that this provision helps improve our oversight of provider networks, which strengthens beneficiary protections. Therefore, we believe the added burden of requiring applicants to demonstrate compliance with network adequacy standards is justified, particularly in light of the flexibilities, discussed later in this section, that we are adopting for how applicants for new MA contracts or expanded service areas can demonstrate compliance with the network adequacy requirements.

Comment: Many commenters did not support our proposal. Commenters expressed concerns over the proposed timing for the submission and review of initial and service area expansion applicants' networks (during the time of application in mid-February of each year). The commenters believed this timing would be insufficient for MA organizations to build high-quality provider networks, and would negatively impact negotiations with provider groups, giving providers leverage to negotiate higher rates that could increase healthcare costs and reduce benefits. Commenters also suggested that our proposal would disproportionately impact smaller organizations working to expand to certain regional, rural, and medically underserved areas, thereby inhibiting competition among plans and ultimately limiting choice for beneficiaries; some of these commenters also expressed that the proposal would provide an unfair advantage to large health plans with an existing presence in these areas. Several commenters posited that our proposal would place a substantial administrative burden on MA organizations and on providers, and that establishing contracts with organizations takes a significant amount of time. Finally, a number of commenters asked CMS to consider allowing MA organizations to use Letters of Intent (LOIs) to contract with providers as a means to meet network adequacy standards, and in order to provide flexibility as they work to come into compliance for the coverage year.

Response: We appreciate the commenters' feedback regarding our proposal. As we noted in the proposed rule, we understand that requiring an MA organization to establish a full provider network almost a year in advance of the contract becoming operational will be difficult. We also indicated that we previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational. While we believe evaluating provider networks at the time of application is important, we agree that some flexibility is appropriate to address this challenge for applicants.

Therefore, based on the comments received, we are modifying the regulation to allow LOIs to be used in lieu of signed provider contracts, at the time of application and for the duration of the application review. The LOI must be signed by both the MA organization and the provider with which the MA organization intends to negotiate. Further, applicants must notify CMS of their use of LOIs to meet network standards and submit copies (upon request) of the LOIs in the form and manner directed by CMS. At the beginning of the contract year, the MA organization must be in full compliance with the section, including having signed provider and facility contracts in place of the LOIs.

CMS would also require any MA organization that utilized LOIs for the application of a new or expanding service area to participate in the triennial review to evaluate compliance with network adequacy standards. This triennial review by CMS will occur during the first year a plan is operational in its new service area.

Comment: Many commenters supported our proposal to allow a 10-percentage point credit at the time of an MA organization's application and during the application review. Some of these commenters recommended that the credit no longer apply once the contract is operational. Some of the commenters expressed the view that the proposed 10-percentage point credit struck the right balance between showing sensitivity to the challenges for MA organizations in developing and submitting provider networks on a much earlier timeline as part of the application process and demonstrating awareness of the need for CMS to monitor the adequacy of MA organizations' provider networks.

A number of commenters noted that the 10-percentage point credit would not be sufficient to make an impact on meeting network standards, especially in rural and other areas with limited providers. Some commenters suggested that we increase the 10-percentage point credit without specifying what percentage point they would prefer, whereas others suggested that we increase the credit to a 20-, 30-, or higher percentage point credit. A commenter noted that the credit undermines CMS's effort to improve network adequacy. A commenter requested clarification on whether other credits would be affected by the proposed 10-percentage point credit for initial and service area expansion applicants.

Response: We thank commenters for their support of this proposal and acknowledge the concerns that were raised by other commenters. As we indicated in our proposal, we understand that organizations may have difficulties meeting this timing for submission of a full provider network. Therefore, in order to provide flexibility to organizations as they build their provider networks, we proposed to allow the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. We believe a 10-percentage point credit, in conjunction with use of Letters of Intent (LOIs), as discussed above, will provide MA organizations with enough flexibility to meet network adequacy standards within the application timeframe.

We also clarify that the 10-percentage point credit would be separate from and in addition to any other applicable credit established in § 422.116(d).

Comment: A few commenters suggested that CMS allow MA organizations to apply for additional time to meet network adequacy standards for initial and service area expansion applicants. A few commenters suggested that CMS delay

implementation of this proposal until 2025.

Response: We believe that allowing the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards and allowing the use of LOIs in lieu of signed contracts, as discussed previously in this rule, for the contracted network in the pending service area, at the time of application and for the duration of the application review, provide sufficient flexibility for MA organizations. We also believe that establishing these changes for the 2024 coverage year will allow us to improve our oversight and effectiveness of network adequacy reviews in a timely fashion.

After careful consideration of the comments received from various stakeholders and for the reasons set forth in our responses and in the proposed rule, we are finalizing, with modifications, the following changes to § 422.116:

- Revise § 422.116(a)(1)(ii) to provide that beginning for contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.
- Add a new paragraph at § 422.116(d)(7), with the heading ''New or expanding service area applicants.'', to provide that beginning for contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use an LOI, signed by both the MA organization and the provider or facility with which the MA organization has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards, in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of the LOIs no longer apply, and if the application is approved, the MA organization must be in full compliance with this section, including having signed contracts with the provider or facility.

D. Part C and Part D Quality Rating System

This final rule finalizes a technical change at § 422.166(i)(12) proposed in the January 2022 proposed rule to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set (HEDIS) measures that are based on the Health Outcomes Survey (HOS). It also finalizes provisions adopted in the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC to enable us to calculate the 2021 and 2022 Star Ratings due to the COVID–19 pandemic.

1. Background

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and the collection of different types of quality data under section 1852(e) of the Act. The Star Rating system for MA and Part D plans is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Rating system, as codified at § 417.472(k). We use different data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans (for example, §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156). The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively.

The Star Ratings are generally based on measures of performance during a period that is 2 calendar years before the year for which the Star Ratings are issued; for example, 2023 Star Ratings will generally be based on performance during 2021. For some measures, such as the cross-sectional measures collected through the HOS, Star Ratings are based on performance up to 3 calendar years prior to the Star Ratings year. For example, the HOS administered in 2021 asked about care received (for example, whether a healthcare provider advised the member to start, increase, or maintain their level of exercise or physical activity) in the 12 months prior to the survey's administration—that is a period of time covering parts of the 2020 and 2021 calendar years—and the data will be used for the 2023 Star Ratings.

In the March 31st COVID–19 IFC (85 FR 19230), we adopted a series of changes to the 2021 and 2022 Star Ratings to address the disruption to data collection and impact on performance for the 2020 measurement period posed by the public health emergency (PHE) for COVID–19. The Star Ratings changes adopted in that rule addressed both the needs of health and drug plans and their providers to curtail certain data collections and adapt their current practices in light of the COVID–19 PHE and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. As explained in the March 31st COVID–19 IFC, we expected to see changes in measure-level scores for the 2020 measurement period due to COVID–19-related healthcare utilization, reduced or delayed non-COVID–19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID–19 inpatient utilization. The March 31st COVID–19 IFC made some adjustments to account for potential changes in measure-level scores so health and drug plans could have some degree of certainty that the Star Ratings would be adjusted and could continue their focus on patients who were most in need. (See 85 FR 19269 through 19275 for a description of the various adjustments.)

The March 31st COVID–19 IFC amended, as necessary, certain calculations for the 2021 and 2022 Part C and D Star Ratings to address the expected impacts of the COVID–19 PHE on data collection and performance in 2020 that were immediately apparent. As the PHE for COVID–19 progressed in 2020 with ultimately all areas across the country eligible for Star Ratings disaster adjustments for extreme and uncontrollable circumstances under the current regulations (§§ 422.166(i) and 423.186(i)) for the 2022 Star Ratings, it became apparent that a modification to the existing disaster policy was required in order to calculate cut points for non-CAHPS measures for the 2022 Star Ratings.

We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. Under §§ 422.166(i)(9)(i) and

(i)(10)(i) and 423.186(i)(7)(i) and (i)(8)(i), the numeric scores for contracts with 60 percent or more of their enrollees living in Federal Emergency Management Agency (FEMA)-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance are excluded from: (1) The measure-level cut point calculations for non-CAHPS measures and (2) the performance summary and variance thresholds for the reward factor. The 60 percent rule ensures that any impact of an unforeseen and uncontrollable circumstance on a particular contract (or group of contracts) in a specific geographic area does not affect the ratings for other contracts. As explained in the April 2019 final rule (84 FR 15777), CAHPS measures use a relative distribution and significance testing, rather than clustering, to determine Star Ratings cut points; our testing indicated that when affected contracts were removed from the distribution of measure-level scores, the distribution of the remaining contracts looked very similar, suggesting that the affected contracts are randomly distributed among the rating levels. Additionally, the CAHPS methodology to assign cut points is less sensitive to extreme outliers that may result from the impact of a disaster on contract-level measure scores; thus, the 60 percent rule does not apply to the calculation of cut points for CAHPS measures. When only a small number of counties are designated by FEMA as Individual Assistance areas, application of the 60 percent exclusions means that the performance of other contracts serving larger or other service areas is used to establish the necessary thresholds for Star Ratings for non-CAHPS measures and the reward factor.

Up until the 2022 Star Ratings, disasters for which any Star Rating adjustments had been made were localized, and the 60 percent rule had removed scores from only a small fraction of contracts (that is, less than 5 percent of contracts on average). The unprecedented impact of COVID–19 created a new methodological issue where, without a revision to the existing disaster policy rules for calculating the measure-level cut points for the 2022 Star Ratings, we would not have had enough contracts to reliably calculate the non-CAHPS measure-level cut points. Consequently, CMS would not have been able to assign Star Ratings for all non-CAHPS measures. Similarly, we would not have had enough contracts to reliably calculate the performance summary and variance thresholds for the Reward Factor.

For most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins [83] during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from the HOS, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. (See 84 FR 15772 through 15773 for an example of the timing of disaster adjustments for measures from the HOS.) Although the CAHPS surveys and HEDIS data collection were not completed in 2020 (we did conduct the HOS in 2020 on a later schedule than usual), CAHPS surveys and HEDIS data collection completed in 2021 reflected performance by plans in 2020 during the PHE for COVID–19 and were used in the 2022 Star Ratings.

In the September 2nd COVID–19 IFC (85 FR 54820), we revised the disaster policy rules for calculating the non-CAHPS measure-level cut points for the 2022 Star Ratings so we would be able to calculate the 2022 Star Ratings for these measures (85 FR 54844–47) since all contracts qualified for the extreme and uncontrollable circumstance adjustments due to COVID–19. The change adopted by the September 2nd COVID–19 IFC at §§ 422.166(i)(11) and 423.186(i)(9) removed application of the 60 percent rule and avoided the exclusion of contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas from calculation of the non-CAHPS measure-level cut points for the 2022 Star Ratings. The September 2nd COVID–19 IFC also modified the calculation of the performance summary and variance thresholds for the reward factor so that the threshold calculation would not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. These changes ensured that CMS was able to calculate measure-level cut points for those measures that qualified for the disaster adjustment for the 2022 Star Ratings; calculate measure-level 2022 Star Ratings; apply the ''higher of'' policy for non-CAHPS measures as described at §§ 422.166(i)(3)(iv), (i)(4)(v), (i)(5), and (i)(6)(i) and (iv) and 423.186(i)(3) and (i)(4)(i) and (iv); calculate the reward factor; and ultimately calculate 2022 overall and summary ratings for 2022 Star Ratings and 2023 QBPs. It was critical to adopt these changes to avoid an unworkable result from the current policy in these extraordinary circumstances and so that CMS could measure actual performance for the 2020 measurement period so plans had an opportunity to demonstrate how they were tailoring care in innovative ways to meet the needs of their enrollees during the PHE for COVID–19. Given the unprecedented impacts of the COVID–19 PHE, it was important to be able to calculate the 2022 Star Ratings to help to continue to drive quality improvement for plans and providers.

We proposed in the January 2022 proposed rule a specific provision for 2023 Star Ratings for HEDIS measures derived from the HOS data collection administered in 2021 covering the 2020/2021 period. We address the comments we received on that proposal in section II.D.2. of this final rule. We also address the changes and comments we received in response to the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC in sections II.D.3. and II.D.4., respectively, of this final rule. Per section 1871(a)(3)(C) of the Act, CMS responds to comments on an interim final rule regarding the Medicare program and finalizes the interim rules within 3 years of the issuance of the IFC.

2. Provision Related to the HEDIS Measures Calculated From the HOS From the January 2022 Proposed Rule

In response to the September 2nd COVID–19 IFC, some commenters requested clarification about the measures that come from the HOS and when the disaster policy would be applied in light of how HOS measures receive adjustment after an extreme and uncontrollable circumstance. A few commenters questioned, based on previous logic for disasters and HOS measures, whether we anticipated that the impacted HOS data collection period would not be until 2021 and the ''higher of'' methodology would be applicable to reporting year 2023 for HOS measures. Another commenter noted that using the 2020 Star Ratings as an example, the contracts affected by 2018 disasters received the ''higher of'' logic for most measures; however, the HOS and HEDIS–HOS measures used the ''higher of'' logic only for contracts affected by 2017 disasters. The commenter stated if this timing applies to 2020 disasters, the HOS and HEDIS–HOS measures will receive the higher of current or prior year measure-level Star Ratings in the 2023 Star Ratings. The

[83] We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

commenters requested clarification since the September 2nd COVID–19 IFC adopted a regulatory change to the 60 percent rule for only the 2022 Star Ratings. We proposed in the January 2022 proposed rule to address the HEDIS measures derived from the HOS used in the 2023 Star Ratings.

As described in the April 2019 final rule (CMS–4185–F) (84 FR 15772 through 15773), for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. Thus, we noted in the preamble to that rule that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances (85 FR 15772 through 15773). Based on the comments received and the timing of the HOS administration, we proposed to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 HOS only, by adding § 422.166(i)(12) to remove the 60 percent rule for affected contracts. This amendment would ensure that we are able to calculate the Star Ratings cut points for the three HEDIS measures [84] derived from the HOS and are able to include these measures in the determination of the performance summary and variance thresholds for the reward factor for the 2023 Star Ratings. Without removing the 60 percent rule for HEDIS measures derived from the HOS, we would not be able to calculate these measures for the 2023 Star Ratings or include them in the 2023 reward factor calculation. By removing the 60 percent rule, all affected contracts (that is, contracts affected by the 2020 COVID–19 pandemic) with at least 25 percent of their enrollees in FEMA-designated Individual Assistance areas at the time of the disaster will receive the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each of the HEDIS measures collected through the HOS as described at § 422.166(i)(3)(iv) for the 2023 Star Ratings.

Below we summarize the comments we received and provide our responses.

Comment: Most commenters expressed support for removing the 60 percent rule for the 2023 Star Ratings for the three HEDIS measures (Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control) derived from the HOS due to the COVID–19 PHE. Commenters noted the detrimental effects of the COVID–19 pandemic on beneficiaries and health care providers and appreciated that this proposed policy would ensure plans are not penalized on these three measures because of the effects of the pandemic.

Response: We thank commenters for their support of this provision. This change to the calculation of ratings for these three HEDIS–HOS measures will permit CMS to calculate these measures for the 2023 Star Ratings and include them in the 2023 reward factor calculation.

Comment: A few commenters requested that HEDIS measures derived from the HOS be removed entirely from the 2023 Star Ratings. They expressed concern that the proposed policy may be inadequate to account for the impacts of the COVID–19 PHE on these measures and that they would be penalized for factors outside of their control.

Response: These three areas—bladder control, physical activity, and reducing falls risk—are important for beneficiaries' health and well-being, even during a PHE. Removing the 60 percent rule will allow most contracts to receive the higher of the 2022 or 2023 Star Ratings (and corresponding measure score) for each of the HEDIS measures collected through the HOS, following the rules at § 422.166(i). This will minimize the impact of the PHE on these measures. It is CMS's view that including these measures in Star Ratings will provide valuable information for people with Medicare on important areas of focus for avoiding serious health problems. As a reminder, as required at § 422.504(o), MA organizations must develop, maintain, and implement business continuity plans, including policies and procedures for disaster or emergency situations. Therefore, we do not believe it is appropriate to eliminate use of these measures entirely in the Star Ratings.

After considering the comments we received, and for the reasons set forth in the proposed rule and in our responses, CMS is finalizing without modification the provision at § 422.166(i)(12) to codify special rules for the calculation of the 2023 Star Ratings for the three HEDIS measures that are collected through the HOS.

3. Provisions in the March 31st COVID–19 IFC

This final rule also responds to comments on and finalizes a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID–19 pandemic (FR 85 19271–19275) that were established in the March 31st COVID–19 IFC. The following is a summary of the provisions and the public comments received on those changes to Part C and D Star Ratings policies included in the March 31st COVID–19 IFC.

a. HEDIS, CAHPS, and HOS Data Collection and Submission for 2021 Star Ratings and 2022 Star Ratings

The March 31st COVID–19 IFC eliminated the requirement to submit HEDIS and CAHPS data at § 422.152(b)(6) for MA contracts and at § 417.472(i) and (j) for cost plans, and to submit CAHPS data at § 423.182(c)(3) for Part D contracts. CMS suspended the collection and submission of HEDIS and CAHPS measures to allow health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during the early stages of the PHE for COVID–19. These actions were adopted to minimize the risk of the spread of infection by eliminating travel and in-person work for the collection of HEDIS data and ensure the safety of CAHPS survey vendor staff by aligning with the CDC's social distancing guidance. Both Part C and D plans could use any data already collected for their internal quality improvement efforts.

CMS also delayed the administration of the HOS until late summer. To address the potential that CMS might not be able to complete HOS data collection in 2020 (for the 2022 Star Ratings), the March 31st COVID–19 IFC also adopted a provision at § 422.166(j)(2)(i) to replace, if the HOS was not conducted in 2020, any measures calculated based on HOS data collections with earlier values from the 2021 Star Ratings that were not affected by the public health threats posed by COVID–19. This specific provision was designed to address any gaps in the necessary HOS data if the HOS could not be administered in 2020. The Star Ratings measures from the HOS include the following: Improving or Maintaining Physical Health; Improving or Maintaining Mental Health; Reducing the Risk of Falling; Improving Bladder Control; and Monitoring Physical Activity.

Comment: Some commenters commended CMS for curtailing HEDIS and CAHPS data collection so that plans and providers could focus on providing care and not put their employees at risk. Other commenters appreciated that by completely eliminating the submission requirements and removing the possibility of a competitive disadvantage as a result of ceasing data retrieval efforts, CMS enabled plans to better focus on patient care and the safety of plans' employees. Commenters

[84] The HEDIS measures derived from the HOS include *Monitoring Physical Activity, Reducing the Risk of Falling,* and *Improving Bladder Control.*

expressed a general understanding of the sensitivity around data collection during this time and the need to focus plans and providers on caring for Medicare beneficiaries.

Response: CMS appreciates the support and emphasis on plans' focus on providing care to Medicare enrollees from the onset of the COVID–19 pandemic.

Comment: Some commenters argued that the HEDIS and CAHPS data collections were already well advanced before shutdowns occurred so there would be little risk to personnel involved in finishing data collection. These commenters stated that HEDIS data collection could be done electronically or through claims analysis and not through in-person contact, thus maintaining social distancing guidance. They also argued that CAHPS survey response rates do not increase much in the last few months of data collection.

Response: The intent of these changes was to eliminate some of the data collection requirements given the public health and safety concerns with collecting the data and to enable plans to focus on the care and safety of their employees and Medicare beneficiaries. Given the extraordinary circumstances under which the healthcare system was operating, CMS wanted plans to have some degree of certainty related to Star Ratings program requirements and wanted to make sure plans would be able to focus on ensuring that Medicare beneficiaries received the care and treatment they needed. The issues facing the healthcare system, including significant differences across regions and demographic groups, created unique challenges for the 2021 and 2022 Star Ratings calculations. Given these concerns, CMS believes that, had the 2020 submission requirements for HEDIS and CAHPS data remained in force, we would not have had complete data for HEDIS and CAHPS across all contracts as needed in order to accurately calculate Star Rating measure cut points for the 2021 Star Ratings. Data collection was ongoing for HEDIS, including medical record review, so not all contracts were near completion.

Data collection was curtailed for CAHPS after the first survey mailing so the data were not complete or representative of all enrollees. In general, for the MA and PDP CAHPS Survey, approximately 40 percent of responses come from the second mailing and telephone follow-up. Further, approximately 50 percent of responses from younger beneficiaries (those under age 55) and black beneficiaries, and 60 percent of Spanish language beneficiary responses, come from the second mailing and telephone follow-up, which were not yet completed at the time the March 31st COVID–19 IFC was issued.

Comment: Commenters were generally supportive of CMS's decision to delay 2020 HOS data collection until late summer 2020, although some commenters wanted all 2020 HOS data collection to be halted. Other commenters recommended CMS move forward with the 2020 administration of HOS, with the stipulation that any data collected be used for internal plan purposes only and not used in the 2022 Star Ratings.

Response: We appreciate the support for delaying the 2020 HOS administration until late summer. The HOS data collection was successfully completed in the fall of 2020. Although the survey was successfully administered, two measures from the HOS, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, were moved to the display page for the 2022 and 2023 Star Ratings due to data validity concerns as described in the HPMS memorandum ''Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings,'' released on August 5, 2021.[85]

Comment: A few commenters agreed with CMS's plan to replace the 2022 Star Ratings for HOS measures with the 2021 Star Ratings if the HOS could not be administered, but some commenters argued plans should have the choice of receiving either the 2021 or 2022 Star Ratings and corresponding scores.

Response: CMS did not have to replace the 2022 Star Ratings with the 2021 Star Ratings for the measures from the HOS since the survey was administered in fall 2020. CMS could not select the higher measure-level star and corresponding numeric data for the measures from the HOS for the 2022 Star Ratings since HOS measures did not qualify for the extreme and uncontrollable circumstances adjustment due to COVID–19 due to the timing and recall periods for the HOS. We are therefore not finalizing the provision at § 422.166(j)(2)(i) which authorized replacement of measures calculated based on HOS data collections for the 2022 Star Ratings with earlier values from the 2021 Star Ratings. Because the HOS was completed in 2020, the provision at § 422.166(j)(2)(i) is moot and it is not necessary to finalize it permanently.

Comment: Some commenters requested that the HOS measures be moved to the display page until at least 2023 or 2024. Additionally, some commenters urged CMS to consider the impact of COVID–19 not only on the 2020 and 2021 HOS data but also on the 2022, 2023, and 2024 Star Ratings. Many commenters stated that even if current conditions improved enough to allow HOS to be fielded in 2020, comparisons of previous and future year scores, as well as comparisons across contracts, would not be valid during the COVID–19 pandemic. A few commenters pointed out that trends will likely vary by region or state based on the prevalence of COVID–19 and the presence or absence of state governments' constraints on patient travel and provider operations. Some commenters argued that it would not be feasible for CMS to adjust HOS outcome measures to account for all COVID-associated factors (for example, social isolation, loneliness, fear of death, national rhetoric regarding the value of elders, economic impacts, and decreased opportunity for physical activities) and pointed out that the negative impacts may last for years. Some commenters did not believe HOS data collected in 2020 would be indicative of overall plan quality, but would instead reflect the massive disruption to the healthcare system caused by the COVID–19 pandemic. To avoid unfairly penalizing plans for circumstances outside their control, most commenters recommended that CMS continue to collect HOS data in 2020 but remove the measures from the Star Ratings for up to 3 years. In particular, commenters were concerned about the two HOS outcome measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health.

Response: Although the HOS data collection was completed as scheduled in fall 2020, CMS agrees that the COVID–19 PHE significantly impacted the validity of the two HOS outcome measures. CMS issued the HPMS memorandum ''Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings,'' on August 5, 2021 announcing that the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures would be moved to the display page on *CMS.gov* with a note that the comparisons were pre- and post-pandemic and that the measures would not be included in the 2022 and 2023 Star Ratings because of validity concerns related to the COVID–19 PHE. These two measures were therefore not included in the 2022 Star Ratings, and

[85] HPMS Memos for WK 1 August 2–6, 2021. CMS.

they will not be included in the 2023 Star Ratings.

After consideration of the public comments we received, we are finalizing without modification the provisions eliminating for 2020 the requirement to submit HEDIS and CAHPS data for MA contracts at § 422.152(b)(6) and for cost plans at § 417.472(i) and (j), and to submit CAHPS data for Part D contracts at §§ 423.156 and 423.182(c)(3). HOS data collection was completed as scheduled in fall 2020; thus, we are not finalizing the provision at § 422.166(j)(2) to replace any measures calculated based on HOS data collections for the 2022 Star Ratings with earlier values from the 2021 Star Ratings that were not affected by the public health threats posed by COVID–19.

b. Adjustments to the 2021 Star Ratings Methodology Due To Lack of HEDIS and CAHPS Data

The March 31st COVID–19 IFC replaced the 2021 Star Ratings measures calculated based on HEDIS and Medicare CAHPS data collections with earlier values from the 2020 Star Ratings (which were not affected by the public health threats posed by COVID–19) at §§ 422.166(j)(1) and 423.186(j)(1).

Comment: Some commenters agreed with CMS that given the impact of the COVID–19 pandemic, CMS should use the 2020 Star Ratings scores and stars in place of 2021 Star Ratings scores and stars. Some commenters stated that such an approach would lessen the impact of any declines in performance that were driven by the PHE and outside of the control of Part C and D sponsors. Further, given that COVID–19 had differential geographic impacts throughout the country, commenters expressed that keeping all plans to the 2020 ratings would keep scoring more stable.

Other commenters recommended that CMS use the 2021 Star Ratings scores and stars. They stated that to not do so would not align with the goal of the program, which is to provide current unbiased and accurate information on the quality performance of a health or drug plan for consumers to make their best health care decisions.

Some commenters also argued that to not use the 2021 Star Ratings would ignore the efforts plans had made during the previous year to significantly improve their HEDIS and CAHPS measure scores. Some commenters stated they disagreed with CMS's statement that measure scores and stars do not fluctuate significantly year to year. They argued that not using 2021 Star Ratings could negatively impact contracts demonstrating year-over-year improvement and ''new'' plans.

Some commenters wanted the choice to use either their 2020 or 2021 Star Ratings. A few commenters suggested that if the 2021 HEDIS and CAHPS measures were not going to be used, these measures should be removed from the 2021 Star Ratings program or moved to the display page.

Response: We believe that the provisions in the March 31st COVID–19 IFC were necessary to ensure public health and safety during this unprecedented time. If we had required plans to collect HEDIS and CAHPS data, plans would have been forced to choose between protecting the safety of those collecting data, potentially diverting resources away from the urgent care needs of Medicare beneficiaries impacted by COVID–19, and collecting data needed by the Star Ratings program.

For the 2021 Star Ratings, there was no reason not to use the most recent data available from all applicable sources. Unlike HEDIS and CAHPS, other data sources for the 2021 Star Ratings were not impacted by COVID–19 and could continue to be used to show recent plan performance. Given that not all data sources were impacted by COVID–19 for the 2021 Star Ratings, and CMS had the ability to calculate the 2021 Star Ratings with the most recent data available for all measures, there was no reason to allow plans to choose if they wanted the 2020 Star Ratings or the 2021 Star Ratings. CMS did not consider moving both HEDIS and CAHPS data to the display page for the 2021 Star Ratings, since that would have resulted in all contracts being rated on only 10 out of 32 Part C measures, which would not reflect the full range of care and services plans provide.

After consideration of the public comments we received, we are finalizing without modification the provisions, as codified at §§ 422.166(j)(1) and 423.186(j)(1), to use the 2020 Star Ratings HEDIS and CAHPS data for the 2021 Star Ratings.

c. Use of 2020 Star Ratings To Substitute for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues

In the March 31st COVID–19 IFC, CMS established a process for the calculation of the 2021 Star Ratings in the event that the impact of the COVID–19 pandemic made it necessary for CMS to focus exclusively on the continued performance of essential agency functions, and the agency did not have the ability to calculate valid and accurate 2021 Star Ratings at §§ 422.164(i), 422.166(j)(1)(v), 423.184(i), and 423.186(j)(1)(iv).

CMS's top priority at the beginning of the pandemic was to ensure public health and safety, including that of beneficiaries, health and drug plan staff, and providers, and to allow health and drug plans, providers, and physician offices to focus on the provision of care. Adopting this provision to address such extraordinary circumstances before they potentially could come to pass in connection with the COVID–19 pandemic ensured that Medicare health and drug plans were aware of the steps CMS would take if we were unable to calculate the 2021 Star Ratings.

Comment: Some commenters supported CMS's proposal to establish modified methods of calculating or assigning 2021 Star Ratings if needed due to potential concerns over the impact of the COVID–19 pandemic on agency functions and the ability to calculate the Star Ratings.

Response: CMS appreciates commenters' understanding of our proposal to establish modified methods for calculating or assigning 2021 Star Ratings in the event that the impact of the COVID–19 pandemic made it necessary for CMS to focus exclusively on the continued performance of essential agency functions, or there were systematic measure-level data issues.

We are not finalizing the proposed provisions at §§ 422.166(j)(1)(v) and 423.186(j)(1)(iv) in this final rule, as CMS was able to calculate the 2021 Star Ratings. We are also not finalizing the special rules for 2021 Star Ratings at §§ 422.164(i) and 423.184(i), as CMS did not identify any data quality issues for non-HEDIS and non-CAHPS measures for the 2021 Star Ratings.

d. Guardrails

CMS modified §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the application of the guardrails for non-CAHPS measures until the 2023 Star Ratings are issued in October 2022. To increase the predictability of the cut points used for measure-level ratings, in the April 2019 final rule (84 FR 15761), we adopted a rule that, starting with the 2022 Star Ratings, guardrails would be implemented for measures that have been in the program for more than 3 years. As specified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), the guardrails ensure that the measure threshold-specific cut points for non-CAHPS measures do not increase or decrease more than 5 percentage points from 1 year to the next. As noted in the April 2019 final rule, the trade-off for the predictability provided by the bi-directional cap is the inability to fully

keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in the overall performance that are greater than the cap would not be reflected in the new cut points. We anticipated that most, if not all, contracts could have had performance changes on certain measures as they dealt with the demands of the COVID–19 pandemic that would result in the guardrails not keeping pace with changes in measure scores across the industry. Given the enormity of the COVID–19 pandemic, CMS believed it was important for plans to be able to focus on patients who were in the most need during the outbreak, and our guardrails, as currently constructed, could have had unintended incentives to the contrary.

Comment: Many commenters agreed with our provision delaying the application of guardrails for non-CAHPS measures until the 2023 Star Ratings. These commenters appreciated that CMS recognized the significant changes in health care utilization that have occurred during the pandemic and that these changes in utilization might persist for some time.

Response: CMS appreciates commenters' support for this provision.

After consideration of the public comments and for the reasons provided in the March 31st COVID–19 IFC and our responses to comments, CMS is finalizing without modification the provisions at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the use of guardrails until the 2023 Star Ratings.

e. Improvement Measures

Another provision of the March 31st COVID–19 IFC expanded the existing hold harmless adjustment for the Part C improvement measures at § 422.166(f)(1)(i) and (g)(3), and for the Part D improvement measures at § 423.186(f)(1)(i) and (g)(3), to include all contracts for the 2022 Star Ratings, not just those with 4 or more stars for their highest rating. At the start of the COVID–19 pandemic, CMS anticipated that the pandemic could cause plan performance during the 2020 measurement period to decline across the nation. Therefore, we believed it was appropriate to adopt a provision to minimize the impact of potential declines in the Part C and D improvement measures. Namely, for the 2022 Star Ratings, if the inclusion of the Part C improvement measure reduced the Part C summary Star Ratings, it would be excluded from the calculation of the summary rating; if the inclusion of the Part D improvement measure reduced the Part D summary Star Rating, it would be excluded from the calculation of the summary rating; and if the inclusion of the Part C and Part D improvement measures reduced the overall Star Ratings, they would be excluded from the overall rating calculation.

Comment: Many commenters supported the hold harmless provision for the Part C and D improvement measures to include all contracts for the 2022 Star Ratings. Some commenters noted that the chaos and disruption brought about by COVID–19, which created unparalleled uncertainty and fear for members regarding health and health care, were likely to eclipse any quality improvement efforts implemented by MA plans during the performance year.

Response: CMS thanks the commenters for their support of this provision.

After consideration of the public comments and for the reasons outlined in the March 31st COVID–19 IFC, CMS is finalizing without modification the provisions at §§ 422.166(g)(3), 423.186(g)(3), 422.166(f)(1)(i), and 423.186(f)(1)(i), to apply the higher ratings after calculating the overall and summary ratings with and without the Part C and/or D improvement measures for all contracts only for the 2022 Star Ratings.

f. QBP Calculations for New Contracts

For the 2021 Star Ratings only, CMS modified the definition of a new MA plan to treat an MA plan as a new MA plan if it was offered by a parent organization that had not had another MA contract for the previous 4 years. New plans that started in 2019 and reported HEDIS and CAHPS data to CMS for the first time in 2020 for the 2021 Star Ratings, because of our elimination of the HEDIS and CAHPS data submissions to CMS, would not have had enough measures to calculate the 2021 Star Ratings and, consequently, the 2022 QBP. A new contract with an effective date of January 1, 2019 would normally have been treated as new for QBP purposes for 2019, 2020, and 2021. The 2022 QBP rating was based on the 2021 Star Ratings, which these new contracts did not have.

Comment: Some commenters supported the modifications made to the definition of a new MA plan for purposes of 2022 QBPs based on 2021 Star Ratings only. However, some commenters stated this modified definition of a new MA plan would penalize new plans, denying them the potential to receive 2022 QBPs. A commenter stated that with respect to placement on the Medicare Plan Finder, new plans would not have the option of earning top billing and placement if they are forced to remain unrated for 2021.

Response: Modifying the definition of a new MA plan as we did in the March 31st COVID–19 IFC does not preclude a plan from receiving a QBP. In the March 31st COVID–19 IFC, we modified the definition of a new plan such that, for purposes of 2022 QBPs based on 2021 Star Ratings only, an MA plan is considered a new MA plan if it is offered by a parent organization that has not had another MA contract for the previous 4 years (rather than 3 years). New plans under parent organizations with other MA contracts would continue to get the enrollment-weighted average of the ratings of the other MA contracts under the parent organization, while new plans under parent organizations that did not have other MA contracts with ratings would continue to be treated as qualifying plans for the purposes of QBPs and would be eligible to receive a QBP percentage increase to the county rate of 3.5 percentage points.

In terms of placement on Medicare Plan Finder, we note that plans are currently sorted first by premium, not by Star Rating.

After consideration of the public comments and for the reasons outlined in the March 31st COVID–19 IFC and our response to comments, CMS is finalizing the definition at § 422.252 without modification, such that for only the 2022 QBP ratings that are based on 2021 Star Ratings, a new MA plan is defined as one that is offered by a parent organization that has not had another MA contract for the previous 4 years.

4. Provisions in the September 2nd COVID–19 IFC

In addition to the provisions discussed in section II.D.3. of this final rule, the September 2nd COVID–19 IFC also adopted a modification to the application of the extreme and uncontrollable circumstances policy for calculation of the 2022 Star Ratings to address the effects of the COVID–19 PHE (85 FR 54844–47). The September 2nd COVID–19 IFC revised the current disaster policy, codified at §§ 422.166(i) and 423.186(i), for 2022 Star Ratings only by: (1) Removing the 60 percent exclusion rule for cut point calculations for non-CAHPS measures; and (2) removing the 60 percent exclusion rule for the determination of the performance summary and variance thresholds for the Reward Factor. As established by the IFC, new § 422.166(i)(11) provides that CMS does

not apply the provisions of § 422.166(i)(9) or (10) in calculating the 2022 MA Star Ratings; and new § 423.186(i)(9) provides that CMS does not apply the provisions of § 423.186(i)(7) or (8) in calculating the 2022 Part D Star Ratings. This change ensured that CMS could: (1) Calculate measure-level cut points for the 2022 Star Ratings; (2) calculate measure-level Star Ratings for the 2022 Star Ratings; (3) apply the ''higher of'' policy for non-CAHPS measures, as described at §§ 422.166(i)(3)(iv) and (i)(4)(v) and 423.186(i)(4)(i), for all contracts with 25 percent or more of their enrollees living in FEMA-designated Individual Assistance areas which included all Part C and Part D contracts operational during the 2020 measurement period; and (4) ultimately calculate overall and summary ratings for 2022 Star Ratings and 2023 QBPs.

The following is a summary of the public comments received on these Part C and Part D Star Ratings policies included in the September 2nd COVID–19 IFC.

Comment: Most commenters supported dropping the 60 percent rule to be able to calculate 2022 non-CAHPS measure cut points and apply the existing adjustment for extreme and uncontrollable circumstances. They expressed support for modifying the disaster policy so that measure-level data for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas during the 2020 performance and measurement period are not excluded from the measure-level cut point calculations for non-CAHPS measures and the performance summary and variance thresholds for the Reward Factor. Given the enormous impact the COVID–19 pandemic has had on the delivery of health care, commenters noted that allowing plans to receive the higher of their measure-level rating from 2021 or 2022 Star Ratings would help ensure that plans are not penalized for declines in performance due to the pandemic.

Response: We thank commenters for their support of these provisions.

Comment: Some commenters requested clarification as to whether the adjustment for extreme and uncontrollable circumstances would apply to the CAHPS measures for the 2022 Star Ratings.

Response: Under §§ 422.166(i)(9) and 423.186(i)(7), CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance from the clustering algorithms. This rule is limited to non-CAHPS measures since CAHPS measures do not use the clustering algorithm. Because the calculation of CAHPS cut points was not impacted by the 60 percent rule, it was not included in the IFC provisions. We did not propose or make any changes to the extreme and uncontrollable circumstance rules for the 2022 Star Ratings for CAHPS measures in §§ 422.166(i)(2) and 423.186(i)(2).

Comment: Some commenters requested clarification about when the disaster policy would apply for the measures from the HOS. A few commenters questioned, based on how the disaster policy has previously applied for the HOS measures, whether CMS anticipated that the impacted HOS data collection period would not be until 2021 and the ''higher of'' methodology would be applicable to the 2023 Star Ratings for HOS measures. Another commenter noted that for purposes of the 2020 Star Ratings, the contracts affected by 2018 disasters received the ''higher of'' logic for most measures; however, the HOS and HEDIS–HOS measures used the ''higher of'' logic only for contracts affected by 2017 disasters. The commenter observed that if this timing applied to 2020 disasters, the HOS and HEDIS–HOS measures would receive the higher of current or prior year measure-level Star Ratings in the 2023 Star Ratings.

Response: We agree with these commenters that the HEDIS–HOS measures should receive the adjustment for extreme and uncontrollable circumstances for the 2023 Star Ratings. We proposed in the January 2022 proposed rule a specific provision for 2023 Star Ratings for HEDIS measures derived from the HOS data collection administered in 2021 covering the 2020/2021 period. In section II.D.2. of this final rule, we finalize these changes for the 2023 Star Ratings for the HEDIS–HOS measures.

Comment: A few commenters suggested that not all plans may be eligible for the extreme and uncontrollable circumstances policy.

Response: All Part C and Part D contracts that were operational during 2020 qualified for the relevant disaster adjustments for the 2022 Star Ratings.

After consideration of the public comments and for the reasons outlined in the September 2nd COVID–19 IFC and our responses to comments, CMS is finalizing without modification the provisions at §§ 422.166(i)(11) and 423.186(i)(9) to codify special rules for the calculation of the 2022 Star Ratings.

E. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505)

CMS has an obligation to ensure the organizations with whom it contracts are able to provide health care services to beneficiaries in a high-quality manner. CMS does not want organizations entering into or expanding in the MA and Prescription Drug programs that are poor performers. Currently, if an organization meets all of the requirements of CMS' MA or Prescription Drug program application, CMS approves the application. However, the application requirements do not look at an organization's prior performance in existing contracts. Therefore, if an organization fails to provide key services or administers the program poorly, their application for a new contract or a service area expansion would still be approved. Allowing poor performers into the MA and Prescription Drug programs puts beneficiaries at risk for inadequate health care services and prescription drugs. To avoid poor performers from entering or expanding, CMS first addressed this issue in the MA and Part D program regulations in 2005. CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Prescription Drug program contract, including for a service area expansion, if that organization has failed to comply with the requirements of a previous MA or Prescription Drug contract. In the April 2011 final rule (75 FR 19684 through 19686), we completed rulemaking that placed limits on the period of contract performance that CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance. In the April 2018 final rule (83 FR 16638 through 16639), we reduced the review period to 12 months. In the January 2021 final rule (86 FR 5864), we established that CMS would only have the authority to deny applications based on an organization's past performance if an organization was subject to an intermediate sanction and/or failed to maintain a fiscally sound operation during the performance review period. Up until the January 2021 final rule (86 FR 5864) CMS issued a sub-regulatory methodology consisting of eleven areas of poor performance, including negative net worth and being under intermediate sanctions during the performance timeframe. The prior methodology assigned ''performance

points'' to organizations for each area the organization failed (for example, had a negative net worth resulted in a performance point). If the total number of performance points reached CMS' threshold the organization's application would be denied based on past performance. Historically, only a handful of applications have been denied based on prior past performance, with three denials since 2017. The low number of denials has not impacted access to MA plans nor do we believe expanding the bases for denials will impact access. In fact, the average number of plans that a beneficiary has access to has been increasing since 2015 with approximately 99.7 percent of beneficiaries currently having access to an MA plan. In addition, 97.7 percent of eligible beneficiaries have access to ten or more plans in CY 2022.

As stated in the January 2021 final rule, CMS' overall policy with respect to past performance remains the same. We have an obligation to ensure MA organizations and Prescription Drug sponsors can fully manage their current contracts and books of business before expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Prescription Drug business to the organization would pose a high risk to the success and stability of the MA and Prescription Drug programs and their enrollees.

The January 2021 final rule limited the bases for denial based on past performance to intermediate sanctions and failure to maintain fiscal soundness. In the proposed rule, CMS sought to expand the bases for application denial to include Star Ratings history, bankruptcy proceedings, and certain CMS compliance actions. CMS also proposed to codify the types of compliance notices which would be used as a factor in CMS' review of an organization's past performance. These notices are Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).

We are codifying the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(C)—Bankruptcy filing or under bankruptcy proceedings, (b)(1)(i)(D)—low Star Ratings, and (b)(1)(i)(E)—Compliance Actions. We are also codifying CMS' compliance actions which are NONCs, WLs, and CAPs in §§ 422.504(m) and 423.505(n). We note that the basis for application denial based on past contract performance is not applicable for MA organizations establishing new D–SNP-only contracts under § 422.107(e) as described in section II.A.6.a.

We proposed to correct a few technical issues identified since the final rule was published in January 2021 and will be codifying those proposals. Specifically, we proposed to correct a drafting error in § 422.502(b)(1)(i)(A) that did not include enrollment sanctions based on medical loss ratios (MLRs) as a basis for an application denial. The technical correction revises § 422.502(b)(1)(i)(A) to also provide for the denial of an application if the organization failed to meet MLR requirements and was prohibited from enrolling pursuant to § 422.2410(c). Secondly, we proposed to correct a minor technical error in § 423.503(b)(1)(i)(A) to remove the word ''to'' when referencing subpart O. Finally, we proposed to modify §§ 422.502(b)(1) and 423.503(b)(1) by deleting ''. . . or fails to complete a corrective action plan during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications. . .'' References to CAPs in §§ 422.502(b)(1) and 423.503(b)(1) were codified more than 15 years ago. Since the original provisions, CMS' corrective action process has changed and is no longer a reason, by itself, to deny an application.

As discussed, we proposed to include in §§ 422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C), as a reason for application denial, organizations that have filed for bankruptcy or are currently in bankruptcy proceedings. Failure to maintain a fiscally sound operation results in enrollees being at risk of not being able to obtain needed medical resources if the organization cannot or will not pay its providers. Similar to being fiscally unsound, an organization that will potentially be declared bankrupt may result in beneficiaries not having access to needed services as providers may terminate contracts when the plan fails to pay for their services or items. Since bankruptcy may result in the closure of an organization's operations, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the MA or Prescription Drug program. Based on this, we believe that any organization that has filed or is in bankruptcy proceedings should not be permitted to expand their current service area or enter into a new contract.

We also sought to include, in §§ 422.502(b)(1)(i)(D) and 423.503(b)(1)(i)(D), a recent history of low Star Ratings as a reason for application denial. We proposed that CMS would deny an application for a new contract or a service area expansion from any organization that received 2.5 or fewer Stars.

CMS' Star Ratings are provided to beneficiaries to help them make informed health care choices. Moreover, MA organizations and Prescription Drug sponsors are required by §§ 422.504(b)(17) and 423.505(b)(26) to maintain summary Part C and/or Part D Star Ratings of at least 3 Stars. Contracts that have 2.5 or less Stars are considered to be ''low performers.'' Regulations at §§ 422.510(a)(4) and 423.509(a)(4) permit CMS to terminate a contract for having less than 3 Stars for 3 consecutive years in a row for Part C summary ratings or for having less than 3 Stars for 3 consecutive years in a row for Part D summary ratings. Such a termination carries with it an exclusion from future MA or Prescription Drug application approvals for 38 months under §§ 422.502(b)(3) and 423.503(b)(3), a more significant consequence than the 1-year application denial we are discussing in this rule. We have decided, based on comments, that a 2-year history of low Star Ratings is a better indicator of poor performance. However, we are clarifying that the applicant' that have 2.5 or less stars for their Part C Summary rating, their Part D Summary rating, or a combination of Part C and Part D Summary ratings for two years be subject to application and service area expansion denials.

Finally, we proposed to codify our practice of issuing compliance notices in §§ 422.504(m) and 423.505(n). CMS also proposed, in §§ 422.502(b)(1)(i)(E) and 423.503(b)(1)(i)(E), to include the receipt of specific types of compliance notices as a reason to deny new applications or applications for service area expansions.

Prior to the January 2021 final rule, CMS included compliance letters as a category in our sub-regulatory past performance methodology. This methodology included NONCs, WLs, Warning Letters with Business Plans, and CAPs. These notices are CMS' formal way of recording an organization's failure to comply with statutory and/or regulatory requirements as well as providing notice to the organization to correct their deficiencies or risk further compliance and enforcement actions.

Of these three types of notices, requests for CAPs are the most serious of the notice types. CMS issues these notices pursuant to §§ 422.510(c) and 423.509(c), which require CMS to afford non-compliant organizations the opportunity to develop and implement a corrective action plan prior to terminating an MA or Prescription Drug

contract. CMS may request CAPs for a one-time egregious error or an organization's continued failure to correct previously identified deficiencies. The non-compliance resulting in a CAP request usually has beneficiary impact, such as failure to process appeals timely or marketing misrepresentation. In cases where CMS requests a CAP where there is no beneficiary impact, the majority are for continued non-compliance with requirements.

WLs are an intermediate level of compliance action, between a NONC and a CAP. WLs, similar to CAPs, are issued for more egregious instances of non-compliance or continued non-compliance. However, the egregiousness or continued non-compliance, at the time of the notice, would not warrant a request for a CAP. Examples include continued failure to timely send Explanation of Benefits, multiple cost/benefit errors on required beneficiary communication documents, and instances of unsolicited marketing.

NONCs are the lowest form of a compliance action issued by CMS. These notices are issued for the least egregious failures. These failures are often a first-time offense, affect a small number/percentage of beneficiaries, or issues that have no beneficiary impact. Examples may include failure to submit and/or attest to agent/broker compensation data or failure to upload or correctly upload marketing materials.

In determining the level of severity of a compliance action, CMS considers whether an organization self-reported the non-compliance. CMS considers items self-reported when CMS would not have otherwise known about the issue. In cases where we direct organizations to take a specific action, such as reviewing and reporting errors in Summary of Benefits (SB) and Evidence of Coverage (EOC) documents, CMS does not consider this self-reporting.

As mentioned above, self-reporting can affect the level of compliance action issued. CMS reviews the organization's non-compliance and whether the organization self-reported the issue or CMS found the issue through means such as, complaint reviews, notification by a State entity, or a review of requested data. Based on the issue involved, CMS determines the appropriate level of compliance that should be issued, such as a WL or a NONC. If the organization did self-report, CMS will consider lowering the level of compliance (for example, issuing a NONC instead of a WL). However, CMS is not required to lower the level of compliance action if the issue was self-reported. This is especially the case with respect to NONCs, where the non-compliance is significant enough to warrant a NONC even if self-reported.

We proposed to assign points to each type of compliance action based on the type of notice and then apply a compliance action threshold to determine if the application should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. CMS will then total the points accrued for each contract, and those applicants that have any single contract with 13 or more compliance action points may have applications for new contracts or service area expansions denied on the basis of past performance.

CMS determined the threshold, by reviewing compliance actions taken from 2017 through November 2021. In the review of this data no more than three organizations, out of over three hundred organizations, scored 13 or more compliance action points in any one year. When looking at a percentile, based on historical data, an organization would need be in the top 2 percent of plans based on compliance action points to accrue 13 compliance action points.

For these reasons, we are finalizing the regulations as proposed, with clarifications regarding compliance actions and modifications to Star Ratings. Below we summarize the comments received and our responses.

Comment: We received numerous comments supporting our provisions.

Response: We appreciate the support for our proposals.

Comment: A few of the commenters who supported our provisions requested CMS take stronger action against plans including reviewing plan governance, civil and criminal penalties, ensuring plans have enough liquid assets to cover liabilities to providers, and reviews of consumer complaints.

Response: CMS appreciates the recommendations and will continue to review performance areas to determine if additional reasons for service area expansions and application denials should be added to future regulations.

Comment: A few commenters suggested that the overall methodology was too harsh and that it would penalize too many plans. A commenter suggested that we limit denials to one contract per Parent organization and do not deny applications of contracts that have less than 10 percent of the Parent organization's total enrollment.

Response: CMS appreciates the suggestion but does not believe it is in the best interest of the program to limit denials to one contract per Parent organization or those contracts with less than 10 percent of the Parent organization's enrollment. The purpose of past performance is to limit the expansion of all poor performing applicants, not just one poor performing contract or only those contracts with significant enrollment. The goal of past performance assessments would be undermined should a Parent organization be allowed to choose which contracts are subject to the past performance evaluation and which are not. The purpose of our past performance evaluation is to ensure that all applicants, regardless of enrollment numbers, are sufficiently qualified to expand into a new service area or enter into a new contract.

Comment: A commenter suggested CMS go back to the past performance methodology prior to the January 2021 final rule, specifically using the outlier percentage threshold for compliance letters and requiring poor performance in more than one category.

Response: CMS appreciates the comment. However, we believe the current and proposed methodology sufficiently identifies poor performers. The previous methodology, using an 80 percent and 90 percent outlier resulted in ''poor performers'' in the compliance category regardless of the number of compliance actions received. A contract with few compliance actions could be considered an outlier based on other contracts having one or two fewer compliance actions. The prior methodology also failed to identify poor performers if many contracts received a significant number of compliance actions. We believe the threshold number appropriately identifies all contracts that are poor performers in the compliance action category. We also do not agree that an applicant should be required to have poor performance in more than one category. We believe failing to meet CMS' requirements for any of our categories is sufficient to determine that the applicant is not qualified to enter into new contracts or expand existing service areas based on their past performance. Therefore, we will continue to deny applications when the applicant fails to achieve sufficient performance in any one category.

Comment: We received a few comments requesting clarification or asking that CMS' Program Audit Corrective Action Plans be excluded from the compliance category.

Response: CMS is clarifying that CAPs resulting from CMS' Program Audits were not included in the compliance action category of our proposal or this final rule.

Comment: We received comments regarding the inclusion of Star Ratings as one of the bases for application denials. A few commenters asked if the Star Ratings used for past performance were the overall Star Ratings or the summary Star Ratings for Part C and Part D. A few commenters requested that CMS use the overall Star Ratings and a few commenters requested that CMS average the parent organization's Star Ratings instead of using the contract-level Star Ratings.

Response: CMS notes that Star Ratings are calculated at the contract level and not the parent organization level. In addition, we note that CMS contracts with a legal entity, not a parent organization. Therefore, averaging all Star Ratings for all contracts under a parent organization would be inconsistent with how CMS contracts with organizations. As for using the overall Star Rating instead of the Part C or Part D Summary rating, CMS notes that our existing termination authority at §§ 422.504(a)(17) and 423.505(b)(26) is based on low ratings for either the Part C or Part D summary rating. Using the overall Star Rating for past performance would be inconsistent with the application of Star Ratings for termination. To ensure clarity, we have modified the regulatory text to clarify that CMS will use the Part C or Part D summary Star rating for past performance purposes.

Comment: Commenters had various concerns regarding Star Ratings in the past performance methodology. A few commenters opposed including Star Ratings in the methodology. Commenters expressed concern that public health emergencies, such as COVID–19, had a negative effect on Star Ratings. A few commenters believe the inclusion of Star Ratings would disincentivize high performing plans from acquiring low performing plans and decrease plan options. Other commenters stated that CMS already has the authority to terminate contracts after three years of low ratings and that should be sufficient. A few commenters suggested that CMS use two years, instead of one year, of Star Ratings in the past performance methodology.

Response: CMS appreciates the commenters' concerns regarding the inclusion of Star Ratings in the past performance methodology. Based on the comments received, we are finalizing our proposal with a modification to require that a contract have two consecutive years of Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings of 2.5 or below to receive a denial of new applications or service area expansions. CMS will use the two most recent Star Ratings period—that is, those that fall in the 12-month lookback period as specified in 42 CFR 422.502(b)(1) and 423.503(b)(1). More specifically, if an organization received a Part C summary rating of 2.5 or below for both of the most recent Star Rating periods, CMS will deny a new application or a service area expansion. The same holds true if an organization received a Part D summary rating of 2.5 or below for both of the most recent Star Rating periods. If an organization received a Part C summary rating of 2.5 or below for one of the Star Rating periods during the most recent lookback period and received a Part D summary of 2.5 or below for the other Star Rating period during the most recent lookback period, CMS will also deny new applications or service areas expansions. For example, for a 2024 application submitted in February 2023, the lookback period will be March 1, 2022 through February 28, 2023, which includes the 2022 and 2023 Star Ratings periods. If the applicant received a summary Star Rating of 2.5 or below for Part C or Part D for the 2022 Star Rating period AND for the 2023 Star Rating period, then the application will be denied. If the organization received a Part C/or Part D summary Star Rating of 2.5 or below only for the 2022 Star Rating period or only for the 2023 Star Rating period, then the application will not be denied.

With respect to commenters' concern that emergencies, such as the COVID–19 pandemic, negatively affect Star Ratings, we note that CMS addresses emergencies, such as COVID–19, in the calculation of Star Ratings using an adjustment for extreme and uncontrollable circumstances policy codified at §§ 422.166(i) and 423.186(i) to mitigate the impact of the disaster on Star Ratings. CMS adopted a number of changes to address expected changes in plan performance due to the COVID–19 public health emergency (PHE) on Star Ratings in the March 31stCOVID–19 IFC (85 FR 19230) and September 2nd COVID–19 IFC (85 FR 54820). Although we expected a decline in measure scores across Star Ratings measures for the 2020 measurement year, we did not see a decline across all measures and saw an increase in scores for a number of measures (see the Fact Sheet—2022 Part C and D Star Ratings[86]). Based on CMS's authority to account for extreme and uncontrollable circumstances, such as the COVID–19, we do not believe the methodology needs to be modified based on issues related to disasters.

[86] Part C and D Performance Data CMS.

Finally, in response to the commenters who believe that plan choices will decrease as a result of our proposed inclusion of low Star Ratings as a basis for application denial, we believe the commenters do not fully understand the proposed methodology. The purpose of the methodology is to prohibit expansions of contracts, not to terminate or decrease the service area of contracts. Based on this, beneficiaries will still be able to enroll or stay enrolled in an existing contract, even though the contract has low Star Ratings. However, the legal entity will not be able to expand into new service areas or add new contracts.

Comment: A few commenters were unsure if the methodology was at the Parent organization level, the legal entity level, or the contract level.

Response: CMS' contract and past performance methodology is calculated at the legal entity level. CMS contracts with a legal entity that covers one or more contracts. If any one of the contracts under the legal entity meets any one of the reasons for denial, all new applications and service area expansions under that legal entity will be denied.

Comment: A few commenters suggested CMS provide MA organizations with an appeal process for compliance actions.

Response: CMS appreciates the need to ensure that compliance actions taken against MA organizations are accurate and appropriate. However, we do not believe an appeal process is necessary. The majority of our compliance actions are data driven, with formal thresholds that define whether an organization receives a compliance action and what level of action is issued. CMS also has an organized process which all potential compliance actions must go through, resulting in greater consistency in the issuance of compliance actions. In addition, when requested by an organization, CMS reviews information provided by the organization and re-reviews the compliance action to determine if the action was appropriate. CMS has a long-standing history of discussing compliance actions with organizations and retracting or modifying compliance actions when necessary. Based on our existing process we do not feel a formal appeals process is necessary for compliance actions. CMS notes that a formal appeal process is available for applicants whose application has been denied for past performance reasons specified in this rule.

Comment: A few commenters were unsure if the compliance action threshold was at the contract level or if

all contract points for the legal entity were added together.

Response: The compliance action point threshold of 13 is at the contract level. We have modified the regulatory text to ensure clarity regarding the point threshold. CMS will review all of the compliance actions and total the points for each contract. If any particular contract under a legal entity has 13 or more compliance action points new applications and service area expansions for that legal entity will be denied.

Comment: A few commenters were concerned that one small contract could affect the entire organization.

Response: CMS acknowledges that one poor performing contract could prohibit an applicant from service area expansions of other contracts or prohibit the applicant from entering into a new contract. As previously stated, if an organization has a poor performing contract it is in the best interest of the program for that organization to focus on improving the performance of the poor performing contract, no matter how small or how few enrollees are in the contract, instead of expanding their footprint. CMS believes all contracts under a legal entity should meet our requirements before that legal entity is permitted to expand into new service areas or add new contracts.

Comment: A commenter stated that CMS should only consider the financial health of the acquiring organization and not of the financial health of the organization being acquired.

Response: Organizations that acquire a poor performing organization are provided a 24-month grace period preceding the subsequent application deadline, after which the performance of the acquired organization will be factored into the acquiring organization's performance. Based on this, if a fiscally sound organization acquires an organization that fails to meet CMS' net worth requirements, the acquiring organization will not be denied the opportunity to expand into new service areas or add new contracts, if the entity was acquired within the 24-month period prior to the application deadline. However, the acquired organization will still be denied. Given the acquired organization has significant fiscal soundness issues, the acquiring organization should be putting all necessary resources into the acquired organization's fiscal soundness issues, rather than trying to expand or enter into new contracts under that legal entity.

Based on the comments received, we are finalizing as proposed with a few modifications. The first modification is to use 2 years of Star Ratings for Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings. The second modification is to clarify that CMS is using the Part C Summary and Part D Summary Star ratings. The final modification is to clarify that the 13 compliance action points are allotted on a per contract basis.

F. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267, and 423.2267)

As discussed in the proposed rule, sections 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to adopt standards related to the review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, sections 1852(c) and 1860D–4(a) of the Act provide that MA organizations and Part D sponsors must disclose specific types of information to each enrollee. Based on these authorities, CMS has promulgated regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in 42 CFR part 422, subparts C (at § 422.111) and V; as well as 42 CFR part 423, subparts C (at § 423.128) and V, as directed in the statutory authority granted to the agency. Additionally, as we noted in the proposed rule, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 also apply to section 1876 cost plans. Finally, CMS has authority to adopt additional contract terms for cost plans (section 1876(i)(3)(D of the Act)), MA plans (section 1857(e)(1)) of the Act), and Part D plans (section 1860D–12(b)(3)(D) of the Act) where such terms are not inconsistent with the Medicare statute and that we determine are necessary and appropriate.

As we did in the proposed rule, because the changes that CMS is finalizing in this section are, unless otherwise noted, applicable to MA organizations, Part D plan sponsors, and section 1876 cost plans, we collectively refer to these entities in this section as ''plans.''

In the January 2021 final rule, entitled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (86 FR 5864), we codified much of the communications and marketing guidance previously found in the Medicare Communications and Marketing Guidelines (MCMG). In this final rule, we are codifying additional guidance and standards from the MCMG that was not part of the January 2021 final rule related to member ID card standards, the limited access to preferred cost-sharing pharmacies disclaimer, plan website instructions on how to appoint a representative, and the website posting of enrollment instructions and forms. In addition, we are codifying several new communications and marketing requirements aimed at further safeguarding Medicare beneficiaries, including reinstating the requirement that plans include a multi-language insert with specified required materials. Finally, we are codifying requirements to address concerns associated with third-party marketing activities.

1. Required Materials and Content

Under § 422.111(i), MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. Likewise, under 1860D–4(b)(2)(A) of the Act and § 423.120(c)(1), a Part D plan sponsor must issue a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs. In the proposed rule, we proposed to codify CMS's current guidance for additional ID card standards, which has historically been issued in the MCMG.

Comment: Most comments that we received on this proposal were supportive. Commenters indicated that including ID cards as required materials will ensure consistency for beneficiaries regardless of the plan in which they enroll.

Response: We acknowledge and appreciate the support for this provision as well as the awareness of the vital nature of the provision.

Comment: We received a comment that pursuant to the existing standards for required materials and context, the ID card would, as a required material, be subject to the 12-point font requirement whereas CMS guidance has previously excluded ID cards from that requirement. Such comment requested

that we continue to exclude the ID card from the 12-point font requirement to which required materials are subject.

Response: We thank the commenter and acknowledge that it would be impractical to require a 12-point font on an ID card. Furthermore, we acknowledge that we have previously (in the MCMG) excluded the ID card from the 12-point font requirement. In addition, we note that CMS has followed the guidance of the Workgroup for Electronic Data Interchange (WEDI) in crafting our required formatting for communications materials. However, as WEDI does not stipulate any requirements for font size, we will not extend our font size requirement to ID cards.

We are codifying the guidance for ID card requirements under §§ 422.2267(e)(30) and 423.2267(e)(32) as proposed, except that in response to the aforementioned comment we are including an additional clarifying at §§ 422.2267(e)(30)(vii) and 423.2267(e)(32)(vii) to exclude the ID cards from the 12-point font size requirement under §§ 422.2267(a)(1) and 423.2267(a)(1). In addition, we have renumbered the remaining required content beginning with the Federal Contracting statement, previously at §§ 422.2267(e)(30) and 423.2267(e)(32).

In the January 2021 final rule, when codifying several other required disclaimers previously provided in the MCMG, Appendix 2, at §§ 422.2267(e) and 423.2267(e), CMS inadvertently left out the disclaimer for Part D sponsors with limited access to preferred cost-sharing pharmacies. In the January 2022 proposed rule, we discussed the importance of this disclaimer and the impact of its omission on Medicare beneficiaries enrolled in Part D plans that only provide access to preferred cost-sharing through a limited number of pharmacies.

Comment: The comments we received on this proposal were supportive.

Response: We acknowledge and appreciate the support for this proposal.

For the reasons set forth in the proposed rule and in response to the supportive comments we received, we are codifying this disclaimer requirement at § 423.2267(e)(40), as proposed.

2. Website Requirements

The regulations at §§ 422.111(h)(2) and 423.128(d)(2) require plans to have an internet website and include requirements regarding posted content. In the January 2021 final rule, we codified additional requirements for plan websites at §§ 422.2265 and 423.2265 based on section 70.1.3 (Required Content) of the MCMG. In doing so, we inadvertently failed to include the requirement that plans post instructions about how to appoint a representative and include a link to a downloadable version of the CMS Appointment of Representative Form (Control Number 0938–0950)), as well as enrollment instructions and forms.

Comment: We received comments supporting this proposal.

Response: We acknowledge and appreciate the support for this provision.

Comment: A commenter noted that CMS did not include the Notice of Dismissal of Appeal in part 423. Additionally, CMS has not included the Notice of Dismissal of Coverage Request in either part 422 or 423. The comment requested that CMS codify both of these notices as indicated.

Response: This comment is outside the scope of the current rule. However, CMS appreciates the observation and will consider this suggestion in future rulemaking. We note that the appeal regulations in subparts M of parts 422 and 423 (for example §§ 422.568(h) and 423.568(j)) address the content requirements for notices of dismissal.

In this final rule, after consideration of the comments received in response to this proposal and for the reasons described in the proposed rule, we are codifying these two requirements as proposed under §§ 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15), respectively.

3. Multi-Language Insert

In the proposed rule, we explained the history of the multi-language insert (MLI) (a standardized document that informs the reader that interpreter services are available in the 15 most common non-English languages in the United States), CMS's previous requirement in the Medicare Marketing Guidelines (MMG) that plans include the MLI with certain materials, and why CMS eventually removed from this requirement for MA plans, Part D sponsors, and 1876 cost plans because it was duplicative of certain notice and tagline requirements implemented by the Office for Civil Rights (OCR) in 2016. Specifically, on May 18, 2016, the OCR published a final rule (81 FR 31375; hereinafter referenced to as the section 1557 final rule) implementing section 1557 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148). Section 1557 of the ACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex (including pregnancy, sexual orientation, and gender identity)), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance; any health program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. Part of OCR's 2016 final rule (81 FR 27778) included the requirement that all covered entities include taglines with all ''significant communications''. The sample tagline provided by the Department consisted of a sentence stating ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).'' in the top 15 languages spoken in a state or states. Because of the inherent duplication with the MLI, CMS issued an HPMS email on August 25, 2016 removing the MLI. On June 14, 2019, OCR published a proposed rule that, among other actions, proposed to repeal the requirement that notices and taglines be provided with all significant communications (84 FR 27846). Finally, on June 19, 2020, OCR published a final rule that finalized the repeal of the notice and tagline requirements while requiring that a covered entity take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals (85 FR 37160, 37210, 37245).

In a proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the February 2020 proposed rule), CMS proposed an availability of non-English translations disclaimer. The disclaimer consisted of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).'' We proposed that the disclaimer be required in all non-English languages that met the five percent threshold for language

translation under §§ 422.2267(a)(2) and 423.2267(a)(2). In addition, when applicable, we proposed the disclaimer be added to all required materials under §§ 422.2267(e) and 423.2267(e). However, we did not finalize the proposed disclaimer in January 2021 final rule (86 FR 5995). In doing so, we stated that CMS believed future rulemaking regarding non-English disclaimers, if appropriate, was best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. We also stated that CMS believed deferring to OCR's oversight and management of any requirements related to non-English disclaimers was in the best interest of the Medicare program.

It is important to note that none of CMS's actions impacting the various notifications of interpreter services changed the requirement that plans must provide these services under applicable law. Plans have long been required to provide interpreters when necessary to ensure meaningful access to limited English proficient individuals, consistent with existing civil rights laws. In fact, in the January 2021 final rule, CMS codified call center requirements under §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) that require interpreter services be provided to non-English speaking and limited English proficient (LEP) individuals at no cost.

In the months following the publication of the January 2021 final rule, we have gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries. The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals sixty-five and older speak a language other than English in the home (*https://data.census.gov/cedsci/table?q=language&tid=ACSST1Y2019.S1603*). CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process. Providing a notification for beneficiaries with limited English proficiency that translator services are available provides a clear path for this portion of the population to properly understand and access their benefits. We have also reviewed complaints in the Complaint Tracking Module (CTM) under the term ''language'' and found several reporting beneficiary confusion based on a language barrier. In retrospect, we believe that solely relying on the requirements delineated in OCR's 2020 final rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs, and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive Medicare benefits through these plans, as well as those already enrolled. Ultimately, we believe it is counterproductive to have regulatory requirements for interpreter services without an accompanying requirement to inform beneficiaries that the service is available.

In the January 2022 proposed rule, we therefore proposed the requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). Similar to the previously required version, the MLI must state ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the 15 most common non-English languages in the United States. In addition, we proposed the requirement that plans also include the required statement in any language that meets the five percent threshold for a plan's service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2) for translation of required materials, when not currently on the standardized MLI. We also proposed the requirement that the MLI be included with all required materials listed in §§ 422.2267(e) and 423.2267(e). Finally, in the January 2022 proposed rule, we explained that if OCR were in the future to finalize broader or more robust requirements associated with interpreter services than what CMS requires and plans adopted those broader or more robust OCR requirements, CMS would consider plans compliant with these MLI requirements.

Comment: Most commenters supported this proposal. Many of these commenters pointed out that individuals who do not speak English are often unaware of their rights. The commenters asserted that having the MLI included with required documents was the best way to reach these individuals.

Response: We acknowledge and appreciate the support. As stated above, we have reviewed CTM cases and found reported beneficiary confusion stemming from not fully understanding materials based on a language barrier. While MA organizations, Part D sponsors, and cost plans are required to provide translator services, the requirement cannot be effective if those organizations do not also inform beneficiaries that those services are available. As we consider certain required documents to be vital to a beneficiary's understanding of the MA, Part D, and cost plan programs, we agree that the requirement to include the MLI with those required documents is the best way to reach the target audience.

Comment: Many commenters suggested different ways to implement this provision including requiring the MLI to be sent with only specific required documents (such as the Summary of Benefits, the Evidence of Coverage, and the Annual Notice of Change), requiring the MLI as a disclaimer on certain required documents, limiting delivery of the MLI to once annually, placing the MLI on the plan's website, and sending the MLI as a small flyer with required documents.

Response: We appreciate the suggested alternate methods. However, we believe that requiring the MLI as a separate full-page document that is included or provided with all required documents is the best way for the MLI to reach the target audience. CMS required plans to provide the MLI under similar circumstances for several years before replacing it with the language assistance notice and tagline requirements adopted in OCR's 2016 final rule. OCR implemented the same dissemination method in its section 1557 final rule from July 18, 2016. Between the MLI and OCR's analogous language assistance notice and tagline requirements, CMS has used this method for over 10 years with positive feedback and few complaints. To reiterate, we are again requiring plan delivery of the MLI to address the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries that exists since OCR repealed the notice and tagline requirements in its June 19, 2020 final rule.

Comment: We received a comment on the MLI indicating a fear that beneficiaries will not read it as they receive a prohibitive volume of paper materials.

Response: For enrollees whose primary language is not English, we are confident, based on historical consumer testing, that they will notice a one-page document, prominently displayed with required documents, directing them how to access support in their chosen language.

After careful consideration of all the comments received, and for the reasons set forth in the January 2022 proposed rule and in our responses to the comments, we are finalizing this provision under §§ 422.2267(e)(31) and 423.2267(e)(33) as proposed.

4. Third-Party Marketing Organizations

In the proposed rule, we discussed our concerns regarding third-party marketing organizations (TPMOs) as well as the reasons for those concerns. We also explained that, while we acknowledge that TPMOs can serve a role in helping a beneficiary find a plan that best meets the beneficiary's needs, additional regulatory oversight is required to protect Medicare beneficiaries from confusing and potentially misleading activities in this space and to ensure that Medicare health and drug plans are appropriately overseeing and maintaining responsibility for the entities that conduct marketing and, potentially, enrollment activities on the plans' behalf. To this end, CMS proposed several updates to various sections of parts 422 and 423, subpart V.

First, we proposed to define TPMOs in §§ 422.2260 and 423.2260 as being organizations that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment, that is the steps taken by a beneficiary from becoming aware of a Medicare plan or plans to making an enrollment decision. In addition, the proposed definition of TPMOs specifies that TPMOs may be first tier, downstream or related entity (FDRs), as defined under §§ 422.504(i) and 423.505(i), but TPMOs may also be other businesses which provide services to customers including an MA or Part D plan or an MA or Part D plan's FDRs. CMS specifically solicited comments from stakeholders regarding the proposed TPMO definition and whether it is sufficiently broad to capture the scope of the types of entities that may be in a position of marketing Medicare health and drug plans. Comments revealed that many of the commenters thought the definition was too broad. Those commenters indicated that they felt the definition would apply to entities to whom it shouldn't apply or would be a burden to compliant organizations instead of applying compliance actions to deter bad actors. There was comment that the definition was too narrow, and that there would be bad actors who were not captured by the definition. We decided, for the reasons discussed in our below response to these comments, that the definition, with clarifying edits described in this final rule, is sufficient for now but may choose to revisit it in future rule-making if the evolving industry landscape indicates that reevaluation is necessary.

Second, we proposed to codify, in §§ 422.2267(e)(41) and 423.2267(e)(41), the requirement that TPMOs use a standardized disclaimer that states ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.'' As part of this proposal, MA organizations and Part D sponsors would need to ensure that any TPMO with which they do business, either directly or indirectly, utilizes this disclaimer where appropriate. MA organizations and Part D sponsors would also need to ensure TPMO's adherence with these requirements through contractual arrangements, review of materials or other appropriate oversight methods available to the MA organization or Part D sponsor such as complaint reviews or audits. CMS would not require the disclaimer for those TPMOs who truly offer every option in a given service area. TPMOs would be required to prominently display the disclaimer on their website and marketing materials, including all print materials and television advertising that meet the definition of marketing. We also would require that the disclaimer be provided verbally, electronically, or in writing, depending on how the TPMO is interacting with the beneficiary. In cases where the TPMO is providing information through telephonic means, the TPMO would be required to provide this disclaimer within the first minute of the call. We believe the proposed disclaimer would help to reduce the type of beneficiary confusion CMS observed when we listened to TPMO-based sales calls.

Third, we proposed to codify new TPMO oversight responsibilities in §§ 422.2274 and 423.2274, covering agent, broker, and other third-party requirements. These requirements would fall under §§ 422.2274(g) and 423.2274(g), with the heading ''TPMO oversight,'' and would work (when applicable) in conjunction with the previously existing FDR requirements in §§ 422.504(i) and 423.505(i). As a part of their oversight responsibilities, plans that do business with a TPMO, either directly or indirectly through an FDR, would be responsible for ensuring that the TPMO adheres to any requirements that apply to the plan. An MA or Part D plan cannot purchase the services of a TPMO, and thereby evade responsibilities for compliance with Medicare marketing and communication requirements. This proposed new requirement that those instances where the TPMO does not contract either directly with the MA organization or the Part D sponsor or indirectly with a plan's FDR, but where the plan or its FDR purchases leads or otherwise receives leads directly or indirectly from a TPMO. It is the responsibility of the MA organization or Part D sponsor to have knowledge of how and from where it (or its FDR) obtains leads or enrollments. We also proposed to require plans (and their FDRs), in their contracts, written arrangements, or agreements with TPMOs, to require TPMOs to disclose to the plan any subcontracted relationships used for marketing, lead generation, and enrollment; require sales calls with beneficiaries to be recorded in their entirety; and have TPMOs report to plans any staff disciplinary actions associated with Medicare beneficiary interaction on a monthly basis. As discussed in the proposed rule, MA organizations and Part D sponsors may not utilize TPMOs as means of evading their own compliance responsibilities, and thus these oversight requirements are intended to require plans to ensure that TPMOs adhere to any requirements that apply to the plans themselves. Based on this, we are finalizing changes to the proposed oversight requirements at §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii) to require that violations by TPMOs of requirements that apply to the MA organization or Part D sponsor be reported to MA organizations and Part D sponsors, in addition to disciplinary actions. These reporting requirements would ensure that plans are made aware of all TPMO-associated activities that are part of or related to the chain of enrollment.

Fourth, we proposed to codify a requirement to provide beneficiaries with certain notifications associated with TPMO lead generating activities. In the proposed rule, we discussed how beneficiaries are receiving outreach from sales agents and brokers based on previous contact and how this outreach in response to the previous contact was not prohibited as unsolicited. We explained the potential for bad actors to abuse this situation, and how beneficiaries were concerned about how the sales agent or broker had obtained the beneficiary's contact information. As part of the proposed rule, plans would be required to ensure that TPMOs conducting lead generating activities inform the beneficiary that his or her information will be provided to a licensed agent for future contact, or that the beneficiary is being transferred to a licensed agent who can enroll him or her into a new plan. This requirement would help to eliminate beneficiary confusion by making the role of lead generating TPMOs more transparent.

Overall, we believe the proposed requirements associated with TPMOs

will result in greater plan oversight of TPMOs, and in turn, will result in a more positive beneficiary experience as it relates to learning about plan choices to best meet their health care needs. We also believe the new requirements will complement and strengthen existing requirements. The finalized disclaimers and notifications will ensure that beneficiaries are more informed. Moreover, the more robust reporting requirements and oversight we now require will create a better mechanism for plans to be made aware when beneficiary-related issues arise.

Comment: We received many comments supporting these proposals. Most of the supporting comments indicated the ''severe'' impact of bad actors in the TPMO industry on the Medicare beneficiary population and the MA and Part D markets. These comments also commended CMS for being accountable and taking action to curtail ''predatory'' activities of these entities.

Response: We acknowledge and appreciate the support of these proposals.

Comment: We received a few comments indicating that these proposed changes are not sufficient as a whole to protect Medicare beneficiaries from the actions of TPMOs. These commenters often suggested that CMS develop mechanisms, best practices, or rules to further curtail the activities of TPMOs. Other commenters suggested CMS create a reporting mechanism specifically for instances where beneficiaries have had detrimental experiences with TPMOs.

Response: We appreciate that the impact of TPMOs on Medicare beneficiaries bears further observation and analysis. As proposed, we believe that these requirements should reduce the incidence of confusing and misleading marketing activities leading to, for example, improper enrollments, by making beneficiaries more well-informed. CMS has a mechanism, through 1–800 Medicare, for reporting detrimental experiences with TPMOs. We review those complaints in our Complaint Tracking Module (CTM). CMS also engages in robust surveillance of agents associated with TPMOs, monitoring their sales and enrollment of beneficiaries. Overall, we have laid the groundwork from which we can develop additional rules addressing potentially confusing and misleading activities in this space, while acknowledging the conscientious performers who act within scope to educate and inform beneficiaries of their healthcare options. While we recognize that our authority to enforce compliance on TPMOs is limited to MA organizations, cost plans, and Part D sponsors, there is room to develop additional parameters around TPMOs as we gain a greater awareness of their impact on the Medicare insurance landscape. We will consider the suggestions made by these commenters as we contemplate future rulemaking.

Comment: We received a comment on this provision indicating that a supporting provision further delineating the difference between educational and marketing events is necessary.

Response: We appreciate this comment. It is, however, outside the scope of this rule. We will consider this suggestion for future policymaking in §§ 422.2264(c) and 423.2264(c) as those sections provide an explanation of the difference between educational events and marketing events.

Comment: We received comments on this provision providing suggestions as to language of the disclaimer the rule requires. Some commenters suggested TPMOs be allowed to modify the disclaimer language to suit individual situations where the operational systems of the TPMO make use of the disclaimer problematic. Some commenters suggested that TPMOs be allowed to modify the disclaimer language when reaching out to individuals with whom they have a business relationship. Some commenters suggested that CMS modify the disclaimer language so that entities cannot incorrectly say that beneficiaries will receive their full Medicare benefits upon enrollment in an MA plan. Some commenters suggested that the language in the disclaimer be more direct, that the disclaimer should make it clear that not all plans and benefits are available in all service areas. Some commenters stated that CMS should require stronger disclaimer language including consideration of provider network and availability of current prescription drugs. Other commenters suggested that the disclaimer contain language referring beneficiaries to other educational tools including *Medicare.gov*, State Health Insurance Programs (SHIPs), and other educational resources.

Response: We respectfully disagree. CMS carefully considered the content and length of this disclaimer, and believes all of it contains vital beneficiary information. The potential burden imposed by reading or listening to this disclaimer is necessary to ensure that plans, and TPMOs engaged in marketing activities on their behalf, are not providing information that could mislead beneficiaries into joining plans contrary to their intention for reaching out, or do not best meet their needs. For example, the TPMO disclaimer makes it clear that the TPMO does not offer all available plans, and that beneficiaries must call 1–800 Medicare or visit *Medicare.gov* for that information. CMS believes it provides the most pertinent information without including more content than a beneficiary can reasonably absorb and understand, especially during the limited duration of a television or radio advertisement. Requiring disclaimer language such as provider networks availability of current prescription drugs, or language referring beneficiaries to other educational resources, while good information, could cause the beneficiary to miss the most pertinent information directly related to the sales and enrollment activities of TPMOs. Furthermore, requiring a standardized notice ensures that all beneficiaries receive the same message, and assists CMS by allowing easier and more robust oversight of that message. The commenters had suggested modifications that either narrowed the scope of the disclaimer beyond what we had intended, or altered the disclaimer such that it no longer matched our intentions. While we received no specific examples of what operational limitations make compliance challenging, we will review specific requests and will consider allowing modifications accordingly. We do not believe that having an existing relationship with a beneficiary reduces the need for him or her to receive the exact information in this disclaimer. Regarding commenters who are concerned about the disclaimer not conveying that enrollees will not receive full benefits upon enrollment, please note that the requirements to not provide inaccurate or misleading information that currently apply to MAOs and Part D sponsors (§§ 422.2262(a)(1)(i), 423.2262(a)(1)(i)) also apply to TPMOs under the proposed TPMO oversight requirements. What we proposed and are finalizing does match what we intended in both definition and scope.

Comment: We received several comments on the definition of TPMOs, including comments requesting additional clarity about what types of entities would be included within this definition. Some commenters indicated that the definition of TPMOs was too broad such that the provisions would apply unfairly to different actors in the Medicare Advantage and Part D plan sales landscape including call center employees and advocates Additionally, some commenters believed the proposed definition of TPMOs was too

narrow. Specifically, some commenters suggested that agents and brokers should be included in the definition of TPMOs. Other commenters suggested that agents and brokers should not be included in the definition of TPMOs. Some commenters suggested we limit the definition of TPMO to those entities with whom plans have a direct relationship. Some commenters suggested we limit the definition of TPMO to those entities who are able to offer all plans in a service area. Some commenters suggested we limit the definition of TPMO to those entities who are able to offer only a specific plan within a service area. Some commenters suggested that the definition of TPMO be limited to only those entities who are contractually obligated to provide services to a plan.

Response: We believe that the definition is clear that TPMOs include all third-party marketers who work on behalf or provide services to plans. The definition is intentionally broad to ensure MA and Part D plans properly oversee and are accountable for any entity who profits in any manner from the enrollment of a beneficiary into an MA or Part D plan. As defined in §§ 422.2260 and 423.2260, this rule would apply to organizations, as well as agents and brokers, that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment. TPMOs may be a first tier, downstream or related entity (FDRs), as defined under §§ 422.2 and 423.4, but may also be entities that are not FDRs but provide services to customers including an MA organization or Part D sponsor or an MA organization's or Part D sponsor's FDR. We have carefully considered the wording of this provision as to the type of entities it encompasses. As described in the proposed rule, our intent is to cover entities that are conducting marketing and/or enrollment activities that result in a beneficiary's enrollment in a Medicare plan, and the definition of TPMO is deliberately broad to accomplish that. With respect to the comments regarding the inclusion of individual agents and brokers in the definition of TPMO, we note that the proposed definition of TPMO included FDRs, which CMS has historically interpreted to mean individual agents and brokers, as well as organizational entities (72 FR 68704). However, because our intention to include individuals including independent agents and brokers was not sufficiently clear, we are finalizing the definition of TPMO at §§ 422.2260 and 423.2260 with an update to clarify that the definition includes such individuals as well as organizations. In addition, we note that definition of TPMOs in the proposed rule included incorrect citations when referencing the regulatory definitions of first tier, downstream, or related entities. These incorrect citations at §§ 422.504(i) and 423.505(i) have been corrected in this final rule to correctly refer to §§ 422.2 and 423.4. We will explore the definition in future rulemaking if we feel that the landscape of the industry evolves such that the definition we are finalizing requires reevaluation.

After careful consideration of all the comments received, and for the reasons set forth in the January 2022 proposed rule and in our responses to the comments, we are finalizing the proposed changes to amend part 422 subpart V and part 423 subpart V with the following modifications. We are updating the TPMO oversight requirements at §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii) to make clear that violations by TPMOs of requirements that apply to the MA organization or Part D sponsor must be reported to MA organizations and Part D sponsors, in addition to disciplinary actions. We are updating the definition of TPMOs at §§ 422.2260 and 423.2260 to include individuals such as independent agents and brokers. We are making a technical correction to the definition of TPMO at §§ 422.2260 and 423.2260 to include correct citations to the definitions of FDRs at §§ 422.2 and 423.4. Finally, we are adding a technical correction that clarifies that ID cards as required documents are exempt from the requirement to have all text in 12-point font. We are finalizing all the other provisions in this section as proposed.

To reiterate and summarize, the new and revised regulatory sections and their content are as follows:

- Sections 422.2260 and 423.2260 are revised to add a definition for Third-Party Marketing Organization (TPMO).
- Sections 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15) are revised to add instructions on how to appoint a representative and to add enrollment instructions and forms.
- Sections 422.2267(e)(30) and 423.2267(e)(32) are revised to add the Member ID card and requirements for the card as a model document.
- Sections 422.2267(e)(31) and 423.2267(e)(33) are revised to add the Multi-Language Insert.
- Sections 422.2267(e)(41) and 423.2267(e)(41) are revised to add the Third-Party Marketing disclaimer.
- Section 423.2267(e)(40) is revised to add the Limited Access to Preferred Cost-Sharing disclaimer.
- Sections 422.2274 and 423.2274 are revised to apply MA and Part D oversight to TPMOs.

G. Regulatory Changes to Medicare Medical Loss Ratio Reporting Requirements and Release of Part C Medical Loss Ratio Data (§§ 422.2460, 422.2490, and 423.2460)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act adopts by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013 **Federal Register**, we published a final rule titled ''Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule), we codified the MLR requirements for MA organizations and Part D prescription drug plan sponsors (Part D sponsors) (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X.

Generally, the MLR for an MA or Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees, prescription drug costs for enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts used to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs, and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR (see

§§ 422.2401 and 423.2401; 422.2420(b)(4) and 423.2420(b)(4); 422.2430(b) and 423.2430(b)).

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately, contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the revenue received by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the Health Care and Education Reconciliation Act (Pub. L. 111–152), also established a new MLR requirement under section 2718 of the Public Health Service Act that applies to issuers of employer group and individual market private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the ''commercial MLR rules.'' Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

We proposed modifications to the MLR reporting requirements in the Medicare Part C and Part D programs and to the regulation that governs the release of Part C MLR data.

2. Reinstate Detailed MLR Reporting Requirements (§§ 422.2460 and 423.2460)

Each year, MA organizations and Part D sponsors submit to CMS data necessary for the Secretary to determine whether each MA or Part D contract has satisfied the minimum MLR requirement under sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act. In the May 2013 Medicare MLR final rule (78 FR 31284) that established the Medicare MLR regulations, CMS codified at §§ 422.2460 and 423.2460 that, for each contract year, each MA organization and Part D sponsor must submit an MLR Report to CMS that included the data needed by the MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract such as the amount of incurred claims, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS under § 422.2410 or § 423.2410.

To facilitate the submission of MLR data, CMS developed a standardized MLR Report template that MA organizations and Part D sponsors were required to populate with their data and upload to the Health Plan Management System (HPMS), starting with contract year (CY) 2014 MLR reporting, which occurred in December 2015. Based on the data entered by the MA organization or Part D sponsor for each component of the MLR numerator and denominator, the MLR reporting software would calculate an unadjusted MLR for each contract. The MLR reporting software would also calculate and apply the credibility adjustment provided for in §§ 422.2440 and 423.2440, based on the number of member months entered into the MLR Report, in order to calculate the contract's adjusted MLR and remittance amount (if any). In addition to the numerical fields used to calculate the MLR and remittance amount, the MLR Report template included narrative fields in which MA organizations and Part D sponsors provided detailed descriptions of the methods used to allocate expenses, including how each specific expense met the criteria for the expense category to which it was assigned.

The proposed rule discussed how CMS originally modeled the Medicare MLR reporting format on the tools used to report commercial MLR data, in keeping with our general policy of attempting to align the Medicare MLR requirements with the commercial MLR requirements to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. The proposed rule also explained how, as part of an initiative to reduce the regulatory burden on private industry, we later amended the reporting requirements by scaling back the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, starting with CY 2018. Under current §§ 422.2460 and 423.2460, for CY 2018 and subsequent contract years, MA organizations and Part D sponsors are only required to report each contract's MLR and the amount of any remittance owed to CMS; they are no longer required to submit the underlying data needed to calculate and verify reported MLR and remittance amount, if any. In the final rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (83 FR 16440, 16675), which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule) and finalized the current MLR reporting requirements, we expressed our belief that we would still be able to effectively oversee MA organizations' and Part D sponsors' compliance with the MLR requirements by relying solely on audits, as authorized under §§ 422.2480 and 423.2480.

As discussed in greater detail in the proposed rule at 87 FR 1903 through 1904, in light of subsequent experience overseeing the administration of the Medicare MLR program while the simplified MLR reporting requirements have been in effect, and after further consideration of the potential impacts on beneficiaries and costs to the government and taxpayers when CMS has limited access to detailed MLR data, we have reconsidered the changes to the MLR reporting requirements that were finalized in the April 2018 final rule. We have come to recognize the limitations of our current approach to MLR compliance oversight, in which we do not collect the information needed to verify that a contract's MLR has been calculated accurately, except in the small number of cases that we can feasibly audit each year. As noted in the proposed rule at 87 FR 1905, we believe we would need to greatly expand the number of audits we conduct if we were to rely on them as our sole means of validating the accuracy of MLR reporting, and we anticipate that the increased cost to the government and the aggregate burden across all of the additional MA organizations and Part D sponsors selected for audits would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements.[87] For these reasons, we proposed to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017. In addition, we proposed to collect additional data on certain categories of expenditures, and to make conforming changes to our data collection tools, which is discussed in section II.G.3. later in this final rule.

[87] The April 2018 final rule (83 FR 16715) estimated that the change in the MLR reporting requirements that CMS finalized for CYs 2018 and subsequent contract years would result in annual savings of $1,446,417 per year ($490,000 to the government and $904,884 to MA organizations and Part D sponsors).

Comment: Many commenters agreed with our proposed reinstatement of the MLR reporting requirements and believe reinstating these requirements will provide transparency to beneficiaries and the public.

Response: We appreciate the support.

Comment: Some commenters expressed opposition to the proposed reinstatement of the Medical Loss Ratio reporting requirement that was previously in effect for contract years 2014–2017. These commenters state that this proposal will add administrative burden. Several commenters expressed concern that more detailed MLR reporting for supplemental benefits will add burden and administrative costs for MA organizations and Part D sponsors. Commenters suggested that CMS require a single consolidated report for supplemental benefits costs rather than a separate report for each benefit. A majority of these commenters suggested that CMS maintain the current simplified MLR reporting requirements that have been in effect since 2018.

Response: We appreciate the feedback. We proposed to reinstate the collection of detailed MLR reporting requirements that were in effect for CYs 2014 through 2017 to improve transparency and oversight concerning the use of Medicare Trust Fund dollars. This requires reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. We address the collection of more detailed data about categories of supplemental benefits in section II.G.3. of this final rule.

In light of subsequent experience overseeing the administration of the Medicare MLR program while the simplified MLR reporting requirements have been in effect, and after further consideration of the potential impacts on beneficiaries and costs the government and taxpayers when CMS has limited access to detailed MLR data, we have reconsidered the changes to the MLR reporting requirements that were finalized in the April 2018 final rule. We have come to recognize the limitations of our current approach to MLR compliance oversight, in which we do not collect the information needed to verify that a contract's MLR has been calculated accurately, except in the small number of cases that we can feasibly audit each year.

In developing the MLR reporting format, CMS modeled the data collection on tools used to report commercial MLR data. This was in keeping with a general policy of modeling the data collection on tools used to report commercial MLR data, with modifications for Medicare-specific needs in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes.

Additionally, given the minimal data we currently receive from MA organizations and Part D sponsors, we believe that we would need to greatly expand the number of audits we conduct if we were to rely on them as our sole means of validating the accuracy of MLR reporting. We would need to conduct comparatively resource heavy audits in order to identify potentially costly errors in the calculation of the MLR and remittance amount, including errors that would have been flagged systematically during the desk review process. We believe that the increased cost to the government and the aggregate burden across all of the additional MA organizations and Part D sponsors selected for audits ($13.8 million per year) would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements ($1.5 million per year). Additional information on the projected cost and burden estimates of auditing MLR reports can be found in the Regulatory Impact Analysis (RIA) pages.

Given that MA organizations and Part D sponsors are already tracking expenses by line of business and contract in order to comply with our current regulations and account for supplemental benefit expenditures for both internal accounting and bid development purposes, we estimate that the additional start-up and ongoing costs and time burden for submitting detailed data will be moderate. We estimate that MA organizations and Part D sponsors will incur minimal one-time start-up costs associated with developing processes for capturing the necessary data and will incur ongoing annual costs relating to data collection, populating the MLR reporting form, conducting an internal review, submitting the MLR reports to the Secretary, and conducting internal audits. Please see additional discussion of these costs in the Collection of Information Requirements section of this rule.

We are finalizing this provision without modification.

3. Changes to Medicare MLR Reporting Regulations, Data Collection Instrument, and Regulations Authorizing Release of Part C MLR Data (§§ 422.2460, 422.2490, and 423.2460)

As noted throughout this section of this final rule, we proposed to amend our regulations to reinstate the MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications. Under our proposed amendments, paragraph (a) of § 422.2460 would state that, except as provided in paragraph (b), for each contract year, each MA organization must submit to CMS, in a timeframe and manner that we specify, a report that includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, including the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410.

We proposed similar amendments to paragraph (a) of § 423.2460, except § 423.2460(a) as proposed would refer to ''incurred claims for covered drugs,'' would omit any mention of ''covered services (both Medicare-covered benefits and supplemental benefits),'' and would refer to the remittance owed to CMS under § 423.2410. In addition, we proposed to revise paragraph (b) of both §§ 422.2460 and 423.2460 to specify that the limited MLR data collection requirements under that paragraph only apply to MLR reporting for CYs 2018 through 2022.

The proposed rule noted that, in connection with our proposal to reinstate the detailed MLR reporting requirements, starting with MLR reporting for CY 2023, we intend to require MA organizations and Part D sponsors to submit their MLR data to CMS using the MLR Reporting Tool that was used to report MLR data for CYs 2014 through 2017, with certain changes. The proposed rule, at 87 FR 1907, discussed the three types of changes that we intend to make to the MLR Reporting Tool:

- First, we will revise the MLR Reporting Tool's formulas to incorporate changes to the MLR calculation that have been finalized since CMS stopped developing the MLR Reporting Tool after CY 2017 MLR Reports were submitted. For example, we will add categories for fraud reduction expenses and medication therapy management programs in the section for Activities that Improve Healthcare Quality,

consistent with changes in the April 2018 final rule that redefined these categories of expenditures as quality improvement activities (83 FR 16670 through 16673). Similarly, we will design the MLR Reporting Tool to automatically calculate and insert the medical savings account (MSA) deductible factor, added to § 422.2440 in a June 2020 final rule (85 FR 33908).

- Second, we will separate out certain items that are currently consolidated into or otherwise accounted for in existing lines of the MLR Reporting Tool. For example, we will separate out low-income cost-sharing subsidy amounts, which were previously subtracted from the MLR numerator and excluded from the denominator, into an information-only line in the MLR Reporting Tool's numerator section.
- Third, we will separate out the single line in the MLR Report for claims incurred during the contract year covered by the MLR Report into separate lines for benefits covered by Medicare Parts A and B, certain additional supplemental benefits (that is, benefits not covered by Part A, B, or D and meeting the criteria in § 422.100(c)(2), but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B), and Part D prescription drug benefits.

The proposed rule noted our intention to require MA organizations to report all expenditures for Medicare-covered benefits, including extended A/B coverage (by which we mean, for example, coverage of additional days during an inpatient stay) and cost-sharing reductions (by which we mean the value of the difference between the cost-sharing under Medicare FFS and the plan's cost-sharing), on the same line of the MLR Reporting Tool, based on our assumption that it would be exceedingly difficult for MA organizations to separately identify and track spending on extended coverage of original Medicare benefits and cost-sharing reductions. We solicited comment on whether this is a reasonable assumption and whether the MLR Reporting Tool should instead mirror how MA bids are submitted under § 422.254(b).

The proposed rule discussed our intention to have MA organizations report expenditures for additional supplemental benefits (supplemental benefits meeting the criteria in § 422.100(c)(2) but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B) on multiple lines of the MLR Reporting Tool, which will represent different types or categories of supplemental benefits. We explained that requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will provide more transparency into how the MLR is being calculated, and it will assist CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. The proposed rule also stated that the public release of information on supplemental benefit spending by benefit type or category may be helpful to beneficiaries who wish to make their enrollment decisions based on a comparison of the relative value of the supplemental benefits actually provided by different MA organizations. We did not propose to require separate reporting of Part D supplemental benefit expenditures (that is, they would continue to be reported combined with other Part D expenditures).

The proposed rule explained that we intend to expand the MLR reporting requirements beyond what was required under the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, to include expenditures related to supplemental benefits. As part of reinstating more detailed MLR reporting, the proposed rule described collecting data on claims incurred for certain supplemental benefits (that is, benefits not covered by Part A, B, or D and meeting the criteria in § 422.100(c)(2), but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B). Based on these considerations, we intend to expand the MLR reporting requirements beyond what was required under the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, to include expenditures related to the following categories of supplemental benefits:

- Dental
- Vision
- Hearing
- Transportation
- Fitness Benefit
- Worldwide Coverage/Visitor Travel
- Over the Counter (OTC) Items
- Remote Access Technologies
- Meals
- Routine Foot Care
- Out-of-network Services
- Acupuncture Treatments
- Chiropractic Care
- Personal Emergency Response System (PRS)
- Health Education
- Smoking and Tobacco Cessation Counseling
- All Other Primarily Health Related Supplemental Benefits
- Non-Primarily Health Related Items and Services that are Special Supplemental Benefits for the Chronically Ill (SSBCI) (as defined in § 422.102(f))

In the proposed rule at 87 FR 1907 through 1908, we discussed the factors that we took into consideration in compiling the list of supplemental benefit types and categories in the proposed rule. We solicited comment on whether the list of supplemental benefit types and categories would be appropriate breakouts for separating out supplemental benefit expenditures in the MLR Reporting Tool. We noted that we were interested in feedback that addressed whether we should increase or decrease the number of types or categories of supplemental benefits, as well as suggestions for alternative categories or for consolidating the previously listed benefit types or categories into larger categories.

We received some comments requesting that requesting that CMS either collapse or expand the proposed supplemental benefit categories. As discussed in our response to these comments, we believe it is more appropriate for CMS to retain flexibility to modify the scope of data fields and the specific list of supplemental benefit categories required to be reported on the MLR Reporting Template. Maintaining this flexibility will allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures and verify and increase accountability for the accuracy of MLR calculation. We are finalizing the amendments to §§ 422.2460(a) and 423.2460(a) to provide us with the flexibility to modify the scope of data fields and categories required for supplemental benefit expenditures. The intent of this rule is not to create a more detailed but static MLR report; rather this rule is intended to enable reporting requirements that support the program needs, such as supporting MLR calculation, verifying data reporting accuracy, gaining insight into supplemental benefit policies, and providing transparency into program expenditure allocation.

In considering the scope of data fields and list of supplemental benefit categories for reporting we will take into account the following four factors, which were previously included in the proposed rule in setting forth our rationale for the list of supplemental

benefit categories. First, data elements and categories should enable a thorough reporting of data elements in categories that support MLR calculation, reduce errors in reporting, and increase our ability to verify data reporting accuracy. Second, data elements and categories for supplemental benefits should be selected to provide transparency into how MA program payments are allocated and may focus on specific benefits, such as the non-primarily health related supplemental benefits offered to the SSBCI population, for the purposes of providing CMS with information on the impact of a specific benefit change. Third, we will take into consideration the percentage of MA plans that offer each type of supplemental benefit in the most recent year for which data on plan benefit packages is available (that is, looking at CY 2022 for developing the CY 2023 Reporting Tool), so that the lines we add to the MLR Reporting Tool are more likely to allow for comparison of MA organizations' expenditures on types of supplemental benefits that are widely offered. In addition, in deciding whether to require separate reporting of the expenditures for a particular supplemental benefit type, we considered the percentage of contracts that currently offer that supplemental benefit under just one plan, as we believe expenditures associated with benefits offered under only one plan under a contract would constitute plan-level data, which CMS proposed to exclude from public release of MLR data consistent with the exclusions for MLR data reported at the plan level and information submitted for contracts consisting of a single plan (see § 422.2490(b)(2)). Fourth in establishing the scope of data fields and categories for supplemental benefits, we acknowledge the trade-offs between the additional information gained from changing requirements and the additional burden placed on MA organizations and Part D sponsors brought about by changing requirements. We will take the balance between the increased value of additional information and the increased reporting burden into account in developing requirements on the scope of data fields and specific list of supplemental benefit categories.

Modifications to the MLR data requirements for supplemental benefits expenditures will be set forth in a revision to the MLR Paperwork Reduction Act package (CMS–10476, OMB 0938–1232) and made available to the public for review and comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

The list of supplemental benefits included in the proposed rule should be viewed as an example of categories of supplemental benefits CMS is interested in collecting and is based on the standards described above. We will set forth data reporting requirements in a revised package as required by the PRA. This package will be published in the **Federal Register** and be available for public comment.

In addition, the proposed rule discussed how we intend to use our authority under §§ 422.2490 and 423.2490 to release to the public the Part C and Part D MLR data we proposed to collect, including the additional data we proposed to collect on supplemental benefit expenditures, to the same extent that we released the information we formerly collected under the MLR reporting requirements in effect for CYs 2014 through 2017. The proposed rule noted that, consistent with §§ 422.2490(c) and 423.2490(c), the release of the MLR data we proposed to collect for a contract year would occur no sooner than 18 months after the end of the applicable contract year, and would be subject to the exclusions in §§ 422.2490(b) and 423.2490(b). We proposed to amend § 422.2490(b)(2) by adding new paragraph (b)(2)(ii), which will exclude from release data on amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit. For example, if only one plan under a contract offers Dental X-rays as a supplemental benefit, and expenditures for that benefit are the only amounts reported on that line of the MLR Reporting Tool, we will exclude the entire amount reported on that line from our public data release. However, if only one plan under a contract covers Dental X-rays, and another plan under that same contract is the only plan under the contract that covers Extractions, expenditures for both benefits will be reported in the Dental line in the MLR Reporting Tool, and that combined amount (assuming both plans had expenditures in the Dental category) will not be excluded from our public data release. As stated in the proposed rule, we believe data regarding supplemental benefit expenditures is only sensitive to the extent that the data reveals plan-level expenditures for a specific benefit offered under a single plan, and that these concerns do not exist when expenditures for multiple types of supplemental benefits or from multiple plans are included in the same line of the MLR Reporting Tool.

We solicited comment on this proposed exclusion, including any suggestions for how we would implement this exclusion (for example, by adding check boxes next to the applicable lines in the MLR Reporting Tool, where users would add a check mark if their expenditures for the supplemental benefit type or category in the line by the checkbox represented expenditures for a single plan and single benefit type), and whether additional exclusions should be added to our MLR data release regulations. We also solicited comment on whether there is additional sensitivity around expenditures for supplemental benefits generally or for any types of supplemental benefits in particular, such that public release of data concerning those expenditures would be harmful.

Comment: A number of commenters supported CMS' efforts to provide additional transparency as part of the proposal to reinstate the detailed MLR reporting previously in effect for contract years 2014–2017. They believed more detailed reporting will demonstrate the value of services being offered to beneficiaries, as included in plan bids, and provide transparency around how rebate dollars are being put to use by plans.

Response: We appreciate the support.

Comment: Some commenters were opposed to the public release of MLR data related to amounts paid for incurred expenditures for supplemental benefits. These commenters do not believe information on expenditures on supplemental services will help beneficiaries effectively distinguish the value offered by different plans.

Response: In the final rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements,'' which appeared in the **Federal Register** on November 15, 2016 (81 FR 80170) (hereinafter referred to as the CY 2017 PFS final rule), we adopted §§ 422.2490 and 423.2490 to authorize the release of MLR reports along with a regulation authorizing release of MA bid data. In that rule, we explained the rationale for releasing MA and Part D MLR reports,

which included increasing transparency and access to Federal data sets, alignment with the public release of MLR data of commercial issuer, facilitating the public evaluation of the evaluation of the MA and Part D programs by providing insight into the efficiency of health insurers' operations, providing beneficiaries with information that can be used to assess the relative value of Medicare health and drug plans, and enhancing the competitive nature of the MA and Part D programs. We further stated that the release of this data would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner. The January 2022 proposed rule acknowledged that this existing regulation for disclosure of MLR reports would include disclosure of the more detailed reports we intended to require beginning with CY 2023. We discussed in that prior rulemaking how we believe that protecting against disclosures of individual beneficiary information and information at the plan level would be sufficient to protect against disclosure of proprietary or confidential commercial information. Disclosure of the additional details about MA supplemental benefits is consistent with the rationale and purpose of §§ 422.2490 and 423.2490. Public access to information on supplemental benefit spending by benefit type or category may be a valuable tool for consumers (to make their enrollment decisions based on a comparison of the relative value of the supplemental benefits actually provided by different MA organization), researchers (to potentially use this data to provide insight on trends in supplemental benefit coverage in the MA programs or to better understand how managed care in Medicare differs from managed care for non-Medicare populations), and the public (to have information at an aggregate level about expenditures and benefits in the Medicare program).

In the proposed rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model'' (81 FR 46162), which appeared in the **Federal Register** on July 15, 2016 (hereinafter referred to as the CY 2017 PFS proposed rule) we enumerated the benefits CMS associated with the release of Part C and Part D MLR data to the public. In that proposed rule, we stated that the release of Part C and Part D MLR data could lead to research into how managed care in the Medicare population differs from and is similar to managed care in other populations (such as the individual and group markets) where MLR data is also released publicly, and could inform future administration of these programs (81 FR 46396). We further stated that the release of this data would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner (81 FR 46397). Notably, in the CY 2017 PFS final rule, in response to comments that requested that CMS release only the MLR percentage for a contract, CMS expressly rejected that approach because releasing only the minimum amount of MLR data for MA and Part D contracts would not align with CMS' release of the detailed MLR data submitted by commercial plans (see 81 FR 80439). However, when we amended §§ 422.2460 and 423.2460 to scale back the MLR reporting requirements starting with CY 2018 MLR reporting, we did not indicate that we had subsequently concluded that MLR data would not provide this value to the public, nor did we acknowledge that a direct consequence of CMS ending the detailed MLR reporting requirements, was that our release of Medicare MLR data would no longer align with the release of commercial MLR data, as we would only be releasing the MLR percentage and remittance amount (if any) for MA and Part D contracts, starting with MLR data submitted for CY 2018.

We believe it is appropriate that we reaffirm our position that the public release of Part C and Part D MLR data provides value to the public both by increasing market transparency and improving beneficiary choice. We believe that the value in CMS releasing to the public detailed MLR data in accordance with §§ 422.2490 and 423.2490, and of alignment with the disclosure of commercial MLR data, provides further support for our proposal to require MA organizations and Part D sponsors to submit such detailed data to us on an annual basis, starting with MLR reporting for CY 2023. Further, while not every beneficiary will use the MLR data as part of making enrollment decisions, we believe providing access to more detailed information about expenditures on supplemental benefits, as reported in the MLR Reporting Tool, will provide a means for beneficiaries to determine the value provided by MA plans.

Overall, we believe that the release of incurred expenditures for supplemental benefits is consistent with the rationale explained in the release of MLR reporting in the 2016 final rule. We do not believe it is necessary or appropriate to create exceptions from this existing regulation to exclude disclosure of the data that will be released for incurred expenditures for supplemental benefits, especially when that data will be provided at an aggregate level without risk of disclosing specific plan-level costs that might be used to put a particular MA plan at a competitive disadvantage.

Comment: A commenter cited that reverting to the requirement to submit more detailed expenditure data on the MLR and the newly added requirement to submit expenditure data on supplemental benefits, in particular, is duplicative of data in the bid pricing tool (BPT).

Response: In our view, the data collected during the bid process and the detailed data collected through the MLR report are not fully comparable. The data collected on the BPT is at the plan benefit package (PBP) level while MLR data is reported at the contract level. MA organizations and Part D sponsors submit bids at the plan level and typically use historical spending and utilization as the basis to for their bid projections for the applicable year. For example, MAOs this June will use 2021 spending and utilization as the basis for trending forwarding their bids to the 2023 plan year. If a plan is new or the MA organization or Part D sponsor expects a significant change in the plan's 2023 enrollment or risk profile, the MA organization or Part D sponsor can use historical 2021 experience from another plan or group of plans that the MA organization or Part D sponsor expects to have had a similar enrollment/risk profile. For this reason, there is not always a one-to-one relationship between the historical plan experience used for bidding for a specific plan and the plan's expenditures in the payment year. For MLR reporting, MAOs submit historical information for a specific contract and

specific contract year, not at the PBP level, so the detailed MLR data is not duplicative of the bid data. In addition, we intend to structure the MLR reporting so that data on supplemental benefits in the detailed MLR report are more granular than the broad supplemental benefit categories used in the BPT. The more detailed categories of reporting for supplemental benefits will provide increased transparency regarding the expenditures on supplemental benefits and enable us to assess the impact of specific policies, such as the provision of non-primarily health related supplemental services to the SSBCI population. Moreover, because the time lag between submission and release of public use files for the MLR data is significantly shorter than the time lag between submission and release of public use files of bid data, users have access to more recent data with the MLR.

The MLR data is typically released for more recent contract years than the BPT data. Under § 422.272(b), MA bid pricing data is released for a contract year that is at least 5 years prior to the upcoming calendar year. In comparison, according to § 422.2490, MLR data cannot be released earlier than 18 months after the end of the applicable contract year. CMS anticipates that for future years, MLR data will be released for more recent years than MA bid pricing data due to these timing requirements.

Comment: Commenters stated that the release of expenditure information on supplemental benefits could risk revealing proprietary cost information and may threaten current MA market competition since supplemental benefits vary between plans, which helps drive competition. Commenters note that given the flexibility around the types of supplemental benefits MAOs may offer and the variety of benefit and payment structures used to offer these benefits, the cost information provided is not ''apples to apples'' across contracts and is not useful for comparison by beneficiaries. As an example, a commenter noted that if only two or three plans in a given area offered a particular benefit category and that information were made publicly available, each plan could readily assess the other's costs and could result in core business strategy and other highly proprietary cost information being revealed.

Response: Currently, §§ 422.2490(b)(2) and 423.2490(b)(2) prohibit release of information that is reported in the MLR reports at the plan level. Our proposal, which we are finalizing, amends that provision to also protect amounts that are reported as expenditures for a specific type of supplemental benefit where the entire reported amount represents costs incurred by the only plan under the contract that offers that benefit. The data will be aggregated at the contract level, rather than at the PBP level, which we believe will prevent releases of proprietary cost information. Additionally, line items in the detailed MLR reporting will include aggregation at the provider type or service level (for example, different types of dental benefits would be reported together as a single line item) in the general supplemental benefit categories. Many MA and Part D contracts cover large or multiple geographic regions or areas and are made up by several plans, avoiding the risk of releasing plan-specific data. As commenters note, the flexibility commenters describe around the types of supplemental benefits MAOs may offer and the variety of benefit and payment structures used to offer supplemental benefits limits the comparability of the data across contracts and therefore, mitigates the risk of revealing proprietary cost information through the release of the supplemental benefit expenditures data. Moreover, as noted in the proposed rule, in deciding whether to require separate reporting of the expenditures for a particular supplemental benefit type, we considered the percentage of contracts that currently offer that supplemental benefit under just one plan, as we believe expenditures associated with benefits offered under only one plan under a contract would constitute plan-level data. In creating a list of potential categories of supplemental benefits for the more detailed MLR reporting, we did not include supplemental benefit types or categories offered by less than 10 percent of all MA plans in 2021, with the exception of SSBCI that are not primarily health related, in order to protect individual plan information. Because of the potential variation in coverage of different items and services, such as the non-primarily health related services provided to the SSBCI population, which can range from indoor air quality equipment to transportation to services supporting self-direction depending on the needs of an individual enrollee whose overall function or health is reasonably expected to be improved by the item or service, we do not believe that the aggregate data available in the MLR reports about expenditures in this category could reveal confidential business strategies or cost information of an MA organization. We will also review the expenditure information on supplemental benefits to gain a better understanding of the data and analyze the number of contracts that include a given supplemental service and take this into consideration in creating files for public use.

Additionally, according to §§ 422.2490(b)(1) and 423.2490(b)(1), narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods, are excluded from MLR data released to the public.

Finally, consistent with §§ 422.2490(c) and 423.2490(c), the release of the MLR data we propose to collect for a contract year will occur no sooner than 18 months after the end of the applicable contract year, and will be subject to the exclusions in §§ 422.2490(b) and 423.2490(b). For example, CMS does not release the narrative for the specifics around spending for any aspect of the MLR, including supplemental benefits per §§ 422.2490(b)(1) and 423.2490(b)(1). Finally, we believe the time lag between submission of data for a given contract year and public release of the data mitigates the potential threat to MA market competition on the basis of supplemental benefits.

Comment: Several commenters cited the challenges of reporting more detailed information on supplemental benefits, and requested CMS delay implementation.

Response: We do not believe that there are sufficient challenges for MA organizations with regard to reporting the more detailed MLR information to delay implementation beyond the MLR report due for CY 2023. Requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will provide more transparency into how the MLR is being calculated, and it will assist CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. In order to ensure accurate MLR reporting, for bid development purposes, and for internal accounting and planning purposes, MA plans presumably already collect detailed information on supplemental benefit expenditures. Given that plans will submit the detailed MLR reports at end of 2024 for contract year 2023, we believe plans will have adequate time to prepare for reporting additional

requirements in the MLR; therefore, a delay in implementation is not warranted.

Comment: A few commenters raised concerns regarding quality improving activities (QIA) and requested that CMS ensure that QIA expenses represent actual value provided for consumers' premium dollars and that plans do not abuse the removal of the ''fraud reduction expenses'' cap.

Response: We appreciate the commenters concerns and remind commenters that the regulations at §§ 422.2430(a)(3) and 423.2430(a)(3) require QIA to be grounded in evidence-based practice that can be objectively measured. Under the current MLR reporting requirements, CMS is unable to determine the extent to which QIA expenses are actually spent on quality improving activities. The more detailed reporting reinstates requirements that plans submit narratives that explain their QIA methodology (for example, there is a line on reporting dedicated to spending on fraud reduction specifically). We believe these reinstated measures will prevent plans from misusing the removal of the fraud reduction cap.

Comment: A few commenters supporting CMS' efforts to reinstate the detailed MLR reporting urged CMS to clarify how health plans should capture and report such information and believed that the claims-based reporting framework may not be appropriate for all supplemental benefits. Commenters stated that using a per member per month (PMPM) reporting system would better illustrate what financial support a plan is providing for such benefits.

Response: We appreciate the feedback. A per member per month (PMPM) reporting of expenditures is not consistent with the general calculation of the medical loss ratio or the method of reporting expenditure information. For the purposes of the MLR, MA organizations and Part D sponsors submit data on incurred claims for each contract, regardless of the type of payment arrangement with providers. The medical loss ratio is calculated by dividing total expenditures (as defined by the MLR instructions and reported to CMS) by total revenues (as defined by the MLR instructions and reported to CMS) for a given contract for a given contract year. A per member per month (PMPM) reporting for selected service categories, such as supplemental services, as suggested by the commenter, would not be suitable for the purpose of the MLR report. We are finalizing the detailed MLR reporting, including flexibility for CMS to change the specific line items and supplemental benefit categories that are reported by MA organizations.

Comment: A few commenters recommended expanding reporting for the ''Non-Primarily Health Related Items that are Special Supplemental Benefits for the Chronically Ill (SSBCI)'' category, and suggested adding sub-categories such as food, transportation, and housing, which align with the broader areas of focus for CMS and health plans.

Another commenter recommended that CMS consolidate the ''Wellness'' and ''Fitness Benefit'' categories, thus establishing a ''Fitness and Wellness Benefit'' category, which would incorporate the programs that use a more holistic approach to the health and wellbeing.

A commenter requested CMS provide clarification on how the ''Fitness Benefit'' should be classified in the MLR reporting, given that currently ''memory fitness'' supplemental benefits are filed as a specific category under the ''Fitness Benefit'' category, as are physical fitness supplemental benefits and wearable device supplemental benefits. They proposed CMS require plans to break out their MLR data across the three categories of fitness benefit, to provide data that evaluate how these very distinct types of fitness benefit are being implemented.

Response: We appreciate the feedback related to expanding and collapsing supplemental benefit categories and line items. As noted above, maintaining flexibility to modify the scope of data fields and categories for MA supplemental benefits will allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures, verify and increase accountability for the accuracy of MLR calculation and accommodate evolving policy and program needs. We describe four standards we will use to determine supplemental benefit data reporting requirements above. One of those standards is the percentage of MA plans that offer each type of supplemental benefit.

With regard to the requests for more detailed reporting for the ''Fitness'' and ''Non-Primarily Health Related Items that are Special Supplemental Benefits for the Chronically Ill (SSBCI)'' categories, as noted in the proposed rule, we proposed to limit separate reporting of expenditures for supplemental benefit types or categories if these services were offered by less than 10 percent of all MA plans in 2021. The exception was the category of services for the SSBCI population that are not primarily health related; we included this category in the proposed rule because we believe this information will help us assess the impact of our 2021 rule change that allows all amounts paid for covered services to be included in the MLR numerator as incurred claims (prior to this rule change, only amounts paid ''to providers''—which is defined in § 422.2 in terms of the provision of healthcare items and services—for covered services could be included in incurred claims, which would have excluded, for example, pest control). We will continue to take the concentration of each type of supplemental benefit category offered into consideration in proposing the list of supplemental benefit categories in the PRA package.

Similarly, with regard to request to combine the ''Wellness'' and ''Fitness'' benefit categories, we will also consider the standard previously described related to the percentage of MA plans offering these specific categories of supplemental benefits.

Generally, as noted previously in this section II.G.3. of the final rule, we will consider the other standards related to administrative burden, data transparency, and data accuracy in developing the proposed reporting requirements in the PRA package.

CMS will propose the MLR data requirements in a PRA package that will be published in the **Federal Register** for public comment. The comment period is 60 days, during which plans and the public may comment on the MLR data reporting requirements. CMS will take these comments into consideration in developing final MLR data reporting requirements, which will be published in final PRA package.

After consideration of the comments and for the reasons outlined in the proposed and final rules and our responses to comments, we are finalizing the proposed amendments to §§ 422.2460(a) and (b) and 423.2460(a) and (b) without modification. We do note for readers that the MLR report will be subject to PRA processes and encourage the submission of comments related to reporting requirements and the structure of MLR reporting once the PRA package is posted for public comment.

In addition, we are finalizing the requirement for MA organizations to separately report expenditures for supplemental benefits (supplemental benefits meeting the criteria in § 422.100(c)(2) but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B) on multiple lines of the MLR Reporting Tool, which will represent different types or categories of supplemental

benefits. Requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will serve program purposes, such as providing more transparency into how the MLR is being calculated, and assisting CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. We did not propose a separate reporting of Part D supplemental benefits expenditures and continue to believe that a separate reporting of Part D supplemental benefits expenditures is not needed at this time. We will set forth detailed reporting requirements through the PRA process as noted previously.

4. Technical Change to MLR Reporting Regulations (§§ 422.2460 and 423.2460)

In addition to our proposal to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications, and to add new data fields to our MLR Reporting Tool as described in the previous section of this preamble, we proposed to make a clarifying amendment to our MLR reporting regulations.

Currently, §§ 422.2460(d) and 423.2460(d) state that the MLR is reported once, and is not reopened as a result of any payment reconciliation process. We proposed to amend this paragraph to note that it is subject to an exception in new paragraph (e), which as proposed will provide that, with respect to an MA organization (in the case of proposed § 422.2460(e)) or Part D sponsor (in the case of proposed § 423.2460(e)) that has already submitted to CMS the MLR report or MLR data submission for a contract for a contract year, paragraph (d) does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Proposed paragraph (e) will also provide that such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, will be regarded as the contract's MLR report or data submission for the contract year for purposes of part 422, subpart X, and part 423, subpart X.

As explained in more detail in the proposed rule at 87 FR 1908 through 1909, we characterized this as a clarifying amendment because we believe it is clear from the discussion in the May 2013 Medicare MLR final rule that the provision stating that the MLR will be reported once, and will not be reopened as a result of any payment reconciliation process, was intended to codify the policy decision that the MLR for a contract year is based on the contract year revenue figure available at the time of reporting, and is not subject to change if the contract year revenues increase or decrease through adjustments that take place in a future year. The proposed rule at 87 FR 1909 discussed this requirement at §§ 422.2460(d) and 423.2460(d) in the context of other provisions in our MLR regulations. We believe this discussion provides additional support for our position that we did not intend to prohibit ourselves from collecting or considering additional or corrected MLR data submitted to address deficiencies or inaccuracies in the original annual MLR submission required under §§ 422.2460 and 423.2460. Specifically, if, based on the data available at the time of the original MLR submission, or on the data that should have been available at the time of the original MLR submission, the MAO or Part D sponsor submits an MLR report or data submission that contains errors or omissions, the MA organization or Part D sponsor must notify CMS of the incorrect report submission. CMS will review and may require a resubmission.

The proposed rule also noted at 87 FR 1909 that a prohibition on any and all corrections or resubmissions would be contrary to our longstanding practice, which dates back to when CMS first began collecting Part C and Part D MLR data (for CY 2014) in December 2015, of allowing MA organizations and Part D sponsors to resubmit their MLR Data Forms for a contract year in order to correct errors and omissions in the original MLR filing without treating that resubmission as a reporting of the MLR for purposes of §§ 422.2460(d) and 423.2460(d).

Comment: A commenter requested additional clarification on CMS' technical changes and proposal for submitting corrections on MLR data. The commenter requested CMS clarify what changes and payment reconciliations would result in requiring an organization to resubmit MLR information and the types of MLR changes that CMS expects plans to report. Further, the commenter requested clarification on any proposed timeline or timing limitations for making changes and how that may correspond with potential audits. The commenter requested further clarification on the materiality thresholds that would trigger the need for a refiling, and examples of what criteria would necessitate a refiling to improve plan compliance. Another commenter expressed concern that requiring MLR corrections as a result of ongoing adjustments, such as direct and indirect remuneration (DIR) adjustments that can be made for years after the initial DIR submission, could require refiling of MLR information for several years. This commenter also asked about the process by which an MA organization or Part D sponsor would resubmit an MLR report.

Response: The general concept underlying the resubmission of an MLR report remains unchanged from our original intent in the May 2013 Medicare MLR final rule. In the proposed rule, we stated that with respect to an MA organization (in the case of proposed § 422.2460(e)) or Part D sponsor (in the case of proposed § 423.2460(e)) that has already submitted to CMS the MLR report or MLR data submission for a contract for a contract year, paragraph (d) does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. We also stated in the proposed rule that our remarks in the 2013 Medicare MLR proposed and final rules made it clear that we never intended to prohibit ourselves from collecting, or taking into account, additional or corrected MLR data that is submitted to address deficiencies or inaccuracies in the annual MLR submission required under §§ 422.2460 and 423.2460. We believe that the remittances owed based on a failure to meet the MLR standard should be based on the revenue and expenditure figures at the time of the report, and should not be subject to change if this revenue or expenditure figure is decreased or increased in a future year. If the revenue or expenditure figures increase or decrease as the result of an omission or other error committed by the MA organization or Part D sponsor, then the entity must notify CMS and may be required to resubmit the MLR report. We understand the commenter's concerns regarding ongoing regularly occurring processes that affect payments, such as the reopenings of Part D payment reconciliation; however, this requirement for notifying CMS of errors in the MLR report does not extend to such adjustments that occur after the MLR report is submitted and finalized. Furthermore, payment reconciliations applicable for a contract year that occur after the contract year MLR report is submitted and finalized would not trigger the resubmission of that MLR report. Based on our prior experience, we do not anticipate that the identification and reporting to CMS

of issues in an MLR report will be commonplace. If we see that organizations are re-stating or correcting MLR submissions that are related to MLR reports that were submitted a number of years ago, then we will revisit this issue. We decline to set a materiality threshold at this time and as we state previously, CMS will review on a case-by-case basis instances in which an MLR report may need to be resubmitted. If CMS decides that an MLR report should be resubmitted, we will provide entities with instructions on how to resubmit at that time.

We assume the commenter who asked about audits is referring to our standard desk review of the MLR reports described at § 422.2460. The resubmission of MLR reports described herein is separate from reporting issues detected through the standard desk reviews of MLR reports. If an error is detected during a desk review, the MLR report is not considered final until it has been corrected and resubmitted and passes the desk review.

Comment: A commenter requested that CMS confirm whether resubmission of an MLR report and/or data may be initiated by CMS only or if resubmission may be initiated by a MA organization or Part D sponsor.

Response: CMS confirms that MLR resubmissions may be initiated by a MA organization, Part D sponsor, or CMS. The regulations we are finalizing at §§ 422.2460(e) and 423.2460(e) specify that CMS can either require or allow an MLR resubmission. We note that upon notification by an MA organization or Part D sponsor of an error in reporting, CMS will work with the reporting entity to gather additional information as necessary and determine whether a resubmission of the MLR report is required.

Comment: A commenter stated that if a plan were at or around the 85 percent threshold when it filed its report, it would be disincentivized from identifying and collecting any erroneous payments after the data submission deadline for fear of subsequently revising its claims estimates, falling below 85 percent, having to refile, and potentially receiving an enrollment penalty.

Response: It is incumbent upon the MA organization or Part D sponsor to submit data that is complete, accurate, and truthful.

MA organizations and Part D sponsors that inaccurately report revenues or expenditures in an MLR filing, taking into account payment policy that was in effect during the contract year and payment amounts that the plan received for that contract year prior to the submission of the MLR report, may be required, as determined by CMS, to resubmit the MLR data for the given contract year. For example, if MA organizations and Part D sponsors identify errors (such as double counting, math errors, or misclassification of a type of revenue or expenditure that is discovered after submission of an MLR report), the organization should contact CMS and may be required to refile as determined by CMS. Additionally, if an MA organization or Part D sponsor develops estimates of revenues or expenditures in preparing the MLR report that are inconsistent with payment policy or MLR guidance in place at the time of submission of the report, the MA organization or Part D sponsor must notify CMS.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing amendments at §§ 422.2460(d) and (e) and 423.2460(d) and (e), as proposed.

H. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

1. Introduction

Under Medicare Part D, Medicare makes partially capitated payments to private insurers, also known as Part D sponsors, for covering prescription drug benefits for Medicare beneficiaries. Often, the Part D sponsor or its pharmacy benefit manager (PBM) receives compensation after the point of sale that serves to lower the final amount paid by the sponsor to the pharmacy for the drug. Under Medicare Part D, this post-point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans. DIR includes rebates from manufacturers, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related to risk-sharing settlements, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan (see § 423.308).

Total DIR reported by Part D sponsors has been growing significantly in recent years. The data Part D sponsors submit to CMS as part of the annual reporting of DIR [88] show that pharmacy price concessions (generally referring to all forms of discounts, direct or indirect subsidies, or rebates that a pharmacy pays to a Part D sponsor to reduce the costs incurred by Part D sponsors), net of all pharmacy incentive payments, have grown faster than any other category of DIR [89] received by sponsors and their contracted PBMs. This means that pharmacy price concessions now account for a larger share than ever before of reported DIR and a larger share of total gross drug costs in the Part D program. In 2020, pharmacy price concessions accounted for about 4.8 percent of total Part D gross drug costs ($9.5 billion), up from 0.01 percent ($8.9 million) in 2010. As shown in Table 2, the growth in pharmacy price concessions from 2010 to 2020 has been a continuous upward trend with the exception of 2011.

[88] CMS collects DIR data under collection approved under OMB control number 0938–0964 (CMS–10174) (''Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment''). CMS does not release publicly the DIR data that we collect. The one exception was a highly summarized release of certain 2014 DIR data related to manufacturer rebates: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.*

[89] Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related risk-sharing settlements, etc.

TABLE 2: PHARMACY PRICE CONCESSIONS BY YEAR (2010–2020)

Contract Year	Total Pharmacy Price Concessions	% Change
2010	$ 8,869,347	–
2011	$8,582,354	-3.2%
2012	$68,086,163	693.3%
2013	$228,573,206	235.7%
2014	$538,421,239	135.6%
2015	$1,719,179,214	219.3%
2016	$2,125,460,000	23.6%
2017	$ 4,001,741,355	88.3%
2018	$6,339,517,817	58.4%
2019	$8,130,024,785	28.2%
2020	$9,535,197,775	17.3%

Source: Summary Direct and Indirect Remuneration Report Data, 2010–2020.

The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400 percent between 2010 and 2020. The data also show that much of this growth occurred after 2012, when the use by Part D sponsors of performance-based payment arrangements with pharmacies became increasingly prevalent. Part D sponsors and their contracted PBMs have been increasingly successful in recent years in negotiating price concessions from network pharmacies. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. Performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

The negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government cost obligations during the course of the payment year, subject to final reconciliation following the end of the coverage year. Under the current definition of ''negotiated prices'' at § 423.100, negotiated prices must include all price concessions from network pharmacies except those that cannot reasonably be determined at the point of sale. However, because performance adjustments typically occur after the point of sale, they are not included in the price of a drug at the point of sale.

As discussed in the proposed rule, based on stakeholder feedback and sponsor-reported DIR data, we understand that the share of pharmacies' reimbursement that is contingent upon their performance under such arrangements has grown steadily each year. When pharmacy price concessions received by Part D sponsors are not reflected in lower drug prices at the point of sale and are instead used to reduce plan liability, beneficiaries generally see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing. Thus, beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

President Biden's Executive Order (E.O.) 14036, ''Promoting Competition in the American Economy'' (86 FR 36987), section 5 (''Further Agency Responsibilities''), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry. Because variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, and given the programmatic impacts laid out above and the charge from the E.O., CMS proposed changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point of sale.

As discussed in the proposed rule, at the time the Part D program was established, we believed, as discussed in the January 2005 final rule (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the price concessions they received. However, in recent years, less than 2 percent of sponsors have passed through any price concessions to beneficiaries at the point of sale. We now understand that sponsors may face market incentives not to apply price concessions at the point of sale because of the advantages that accrue to sponsors in terms of lower premiums (also an advantage for beneficiaries). Pharmacy price concessions reduce plan costs, and having the concessions not be applied at the point of sale reduces plan costs and plan premiums at the expense of the beneficiary having lower cost-sharing at the point of sale, thus shifting some of the net costs to the beneficiary via higher cost-sharing. We believe that Part D sponsors are incentivized to have lower premiums versus lower cost-sharing because anecdotal evidence suggests beneficiaries focus more on premiums instead of cost-sharing when choosing plans.

For this reason, as part of a November 2017 proposed rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56419 through 56428), which appeared in the **Federal Register** on November 28, 2017, we published a ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale.'' In the Request for Information, we solicited comment on whether CMS should require that the negotiated price at the point of sale for a covered Part D drug must include all price concessions that the Part D

sponsor could potentially collect from a network pharmacy for any individual claim for that drug. Of the many comments received, the majority were from pharmacies, pharmacy associations, and beneficiary advocacy groups that supported the adoption of such a requirement claiming that it would: (1) Lower beneficiary out-of-pocket drug costs (especially critical for beneficiaries who utilize high cost drugs); (2) stabilize the operating environment for pharmacies (by creating greater transparency and allegedly making the minimum reimbursement on a per-claim level more predictable); and (3) standardize the way in which plan sponsors and their PBMs treat pharmacy price concessions. Some commenters—mostly Part D sponsors and PBMs—were against such a policy, claiming that it would limit their ability to incentivize quality improvement from pharmacies. In the proposed rule titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses'' (83 FR 62174 through 62180), which appeared in the **Federal Register** on November 30, 2018 (hereinafter referred to as the November 2018 proposed rule), we solicited comment on a potential policy approach under which all pharmacy price concessions received by a plan sponsor for a covered Part D drug, including contingent price concessions paid after the point of sale, would be included in the negotiated price (83 FR 62177). Specifically, we considered adopting a new definition for the term ''negotiated price'' at § 423.100, which would mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary. In the final rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' which appeared in the **Federal Register** on May 23, 2019 (84 FR 23867), we noted that we received over 4,000 comments on this potential policy approach, indicated that we would continue studying the issue, and left the existing definition of ''negotiated prices'' in place.

To address concerns about the lack of transparency in the performance measures used to evaluate pharmacy performance, in the February 2020 proposed rule, we proposed to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. We explained in the proposed rule that, once collected, we would publish the list of pharmacy performance measures in order to increase public transparency. In the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the **Federal Register** on January 19, 2021 (86 FR 5684), we finalized the proposed amendment to § 423.514(a), such that, starting January 1, 2022, Part D sponsors are required to disclose their pharmacy performance measures to CMS.

After considering the comments received on the November 2018 and January 2022 proposed rules, and in light of recent data indicating that pharmacy price concessions have continued to grow at a faster rate than any other category of DIR,[90] applicable beginning with contract year 2024, we are finalizing the policy proposed in the January 2022 proposed rule to amend § 423.100 to define the term ''negotiated price'' to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all possible pharmacy price concessions. Effective January 1, 2024, we will delete the current definition of ''negotiated prices'' (in the plural) and we will add a definition of ''negotiated price'' (in the singular), applicable January 1, 2024, to make clear that a negotiated price can be set for each covered Part D drug. We believe this approach accommodates the different approaches to applying price concessions under sponsor and PBM payment arrangements with pharmacies, which may provide for price concessions to be applied uniformly as a percentage adjustment to the price for all Part D drugs dispensed by a pharmacy or have price concessions differ on a drug-by-drug basis. In addition, defining ''negotiated price'' in the singular is consistent with the regulations for the coverage gap discount program, which define the term ''negotiated price'' at § 423.2305, and it is compatible with our existing regulations, which at times refer to the ''negotiated price'' for a specific drug rather than ''negotiated prices'' for multiple drugs. Second, we will define ''negotiated price'' as the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account pharmacy price concessions. For the reasons described below, we are finalizing these proposals.

[90] From 2018 to 2020, pharmacy price concessions increased by 50.4 percent while all other DIR increased by 23.5 percent.

2. Background

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under the definition of ''negotiated prices'' at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point-of-sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, Part D sponsors can, for the most part, choose whether to reflect in the negotiated price the various price concessions they or their intermediaries receive from all sources, not just pharmacies. Specifically, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' Part D sponsors are allowed, but generally not required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. Under the existing definition of negotiated prices at § 423.100, however, negotiated prices must include all price concessions from network pharmacies that can reasonably be determined at the point of sale.

To date, very few price concessions have been included in the negotiated price at the point of sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year using the form required by CMS for reporting Summary and Detailed DIR (OMB control number 0938–0964). These data on price concessions are used in our calculation of final plan payments, which, under section 1860D–2(d)(1)(B) of the Act, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR. Reinsurance payments under section 1860D–15(b) of the Act, and risk sharing payments and adjustments under section 1860D–

15(e)(2) of the Act are also required to be based on costs actually incurred by Part D sponsors. In addition, pursuant to section 1860D–2(d)(2) of the Act, Part D sponsors are required to disclose the aggregate negotiated price concessions made available to the sponsor by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers.

When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing. In contrast, when price concessions are applied after the point of sale, as DIR, the majority of the concession amount accrues to the plan, and the remainder accrues to the government. For further discussion on this matter, please see the CMS Fact Sheet from January 19, 2017 ''Medicare Part D Direct and Indirect Remuneration,'' found on the CMS website at *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir*. The January 2022 proposed rule explained in detail how pharmacy price concessions applied as DIR can: (1) Lower plan premiums and increase plan revenues; (2) result in cost-shifting to certain beneficiaries (in the form of higher cost-sharing) and the government (through higher reinsurance and low-income cost-sharing subsidies); and (3) obscure the true costs of prescription drugs for consumers and the government.

3. Changes to the Definition of Negotiated Price (§ 423.100)

As discussed in the proposed rule, in the May 2014 final rule (79 FR 29844), we amended the definition of ''negotiated prices'' at § 423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies—with an exception, intended to be narrow, that allowed the exclusion of contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the reasonably determined exception). At that time, we did not anticipate the growth of performance—based pharmacy payment arrangements that we have observed in subsequent years.

The proposed rule discussed how, based on feedback from stakeholders as well as information submitted by plan sponsors in their annual DIR reports, we have come to understand that the reasonably determined exception has been applied more broadly than we had initially envisioned, due to the shift by Part D sponsors and their PBMs towards contingent pharmacy payment arrangements. In short, because performance-based pharmacy payment adjustments are contingent upon performance over a period of time that extends beyond the point of sale, the stakeholders asserted that by definition, the amount of these adjustments cannot ''reasonably be determined'' at the point of sale as they cannot be known in full at the point of sale. As a result, the reasonably determined exception prevents the current policy from having the intended effect on price transparency, consistency (by reducing differential reporting of pharmacy payment adjustments by sponsors), and beneficiary costs.

Given the predominance of plan sponsors' use of performance-contingent pharmacy payment arrangements, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves the goals previously discussed: Meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and preventing cost-shifting to beneficiaries and taxpayers. Therefore, to establish a requirement that accomplishes these goals while better reflecting current pharmacy payment arrangements, we proposed to delete the existing definition of the term ''negotiated prices'' at § 423.100 and add a definition of the term ''negotiated price'' at § 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum possible reduction that could result from any contingent pharmacy payment arrangement). Specifically, as noted previously, we proposed to delete the current definition of ''negotiated prices'' (in the plural) and to add a new definition of ''negotiated price'' (in the singular) in order to make clear that a negotiated price can be set for each covered Part D drug, and the amount of pharmacy price concessions may differ on a drug-by-drug basis. Our proposed definition of negotiated price would specify that the negotiated price for a covered Part D drug must include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts (such as incentive fees) if these amounts increase prices. Under our proposal, we would not change Part D sponsors' ability to pass through other, non-pharmacy price concessions and other direct or indirect remuneration amounts (for example, legal settlement amounts and risk-sharing adjustments) to enrollees at the point of sale. These proposed provisions are discussed in the following sections.

a. All Pharmacy Price Concessions

In the proposed rule, we proposed to adopt a new definition of ''negotiated price'' at § 423.100 that would include all pharmacy price concessions received by the plan sponsor for a covered Part D drug. The proposed definition would omit the reasonably determined exception, meaning that all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted PBMs, would have to be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such price concessions are contingent upon performance by the pharmacy.

Section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). Although we continue to believe that the prior interpretation of ''take into account'' was permissible, we believe that our initial interpretation may have been overly definitive with respect to the intended meaning of ''take into account.'' We believe that a proper reading of the statute supports requiring that all pharmacy price concessions be applied at the point of sale. As proposed, requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices ''take into account'' at least some price concessions and, therefore, would be consistent with and permitted by the plain language of section 1860D–2(d)(1)(B) of the Act.

The proposed rule noted that the regulatory change we proposed would change the reporting requirements for Part D sponsors, but it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point of sale. Contracts between sponsors or their PBMs and pharmacies can continue to provide for performance-based payment adjustments. The requirement that pharmacy price concessions be passed through to the point-of-sale price only

directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments.

Comment: Most of the comments we received supported the adoption of a requirement that pharmacy price concessions be applied to the negotiated price at the point of sale. Many of the commenters who supported the proposal agreed that Part D sponsors or the sponsor's intermediaries apply the ''reasonably determined'' exception in the current definition of ''negotiated prices'' to nearly all performance-based pharmacy payment adjustments and that the exclusion of these adjustments from the negotiated price has resulted in cost-shifting to beneficiaries and the government. A majority of the commenters agreed with our assessment that the requirement to include all pharmacy price concessions in the negotiated price at the point of sale would lead to lower overall beneficiary spending for prescription drugs, even after accounting for possible increases in beneficiary premiums.

Many commenters explained that they supported the proposal because they believed it would increase price transparency for beneficiaries, the government, and other stakeholders. Several commenters agreed with our observation in the proposed rule that there is currently wide variation in reporting of DIR to CMS, with some, albeit few, plan sponsors including certain pharmacy price concessions in negotiated price, while others continue to report them as DIR. Some commenters suggested that this inconsistency in reporting makes it difficult for beneficiaries to accurately compare plans with respect to the true costs of their medications. These commenters suggested that requiring all pharmacy price concessions to be accounted for in negotiated price would enhance the quality of information available to beneficiaries and provide them with a better understanding of how they will progress through the phases of the Part D benefit based on their current medications. Several commenters believed that increased price transparency would also create a more level playing field among plans by providing more consistency in how Part D sponsors report these price concessions. Many commenters suggested that pharmacies would also benefit from the increased price transparency because it would provide information necessary for more accurate budgeting and improved ability to evaluate proposed PBM contracts.

Response: We thank these commenters for their support and agree that changing the definition of ''negotiated price'' will provide greater transparency and lower out-of-pocket costs for beneficiaries.

Comment: Some commenters stated that the policy would harm competition among pharmacies, leading to higher program costs. These commenters explained that under a revised definition of ''negotiated price,'' sponsors would no longer be able to apply pharmacy price concessions as DIR to reduce plan premiums. Several commenters stated that plan sponsors have demonstrated that the use of preferred networks has put a downward pressure on net prices and noted that pharmacies aggressively compete for preferred status in low premium plans. Knowing that beneficiaries prefer these plans, pharmacies (and, in particular, large retail-based pharmacies) are willing to offer substantial concessions to ensure that they have access to a large and fast-growing membership base. These commenters suggested that beneficiaries are not as sensitive to—or aware of—point-of-sale negotiated prices in comparison to premiums, and if sponsors are no longer able to reduce premiums by applying pharmacy price concessions as DIR, the result will be less effective competition between pharmacies for network placement. These commenters concluded that the use of post-point-of-sale pharmacy price concessions can give sponsors further leverage with pharmacies to negotiate prices, which decreases costs for the entire program.

A few commenters were concerned that including pharmacy price concessions in the negotiated price would give pharmacies the power to impact future discount levels and pharmacies' increased negotiating power would dramatically impact costs for patients, taxpayers, and plans. A few commenters suggested that pharmacies would not agree to economically equivalent discounts and would use the ''any willing provider'' provisions to mandate that they must be allowed to participate in the network even at less of a discount.

Response: The comments contending that sponsors' inability to apply pharmacy price concessions as DIR to reduce premiums will lead to less effective competition among pharmacies for network placement assume that post-point-of-sale recoupments are a more effective incentive than post-point-of-sale bonus payments. Commenters did not cite evidence to support this assumption; therefore, we believe pharmacies would continue to have incentives to compete for placement in networks. In addition, the aggressive competition among pharmacies for placement in low premium plan networks would be a continuing incentive for plan sponsors to keep premiums as low as possible regardless of the change in how the negotiated price is reported to CMS. To the extent that this policy results in increased transparency and information symmetry it would encourage market competition and improve competition among pharmacies.

As noted above, several commenters stated that plan sponsors have demonstrated that the use of preferred networks has put a downward pressure on net prices, and we see no reason why this would change under the new policy. In spite of the statutory requirement at section 1860D–4(b)(1)(A) of the Act that Part D sponsors permit the network participation of any pharmacy willing to accept their standard terms and conditions, Part D sponsors and pharmacies remain free to negotiate terms of preferred network participation. The commenters provided no evidence to support the assertion that post-point-of-sale incentive payments (if used) would provide any less effective an incentive for pharmacies to continue to compete for preferred network status. We believe the policy would improve transparency and not necessarily affect any party's leverage.

Comment: We received some comments that opposed the adoption of a requirement that all pharmacy price concessions be included in the negotiated price at the point of sale because it would lead to higher premiums and increased government costs. Several commenters stated that the financial and budgetary impact of revising the definition of negotiated price to include all pharmacy price concessions does not address the Administration's objectives to reduce overall drug prices. A few commenters noted that the CMS impact analysis estimates that drug manufacturers would have a financial gain due to less liability during the coverage gap. These commenters stated that this is particularly concerning as it financially rewards the very industry responsible for high drug prices. A few commenters posited that any savings from the policy would not be distributed evenly among beneficiaries. The commenters noted that although a subset of beneficiaries would pay less for discounted drugs, other beneficiaries would only experience higher premiums. The

commenters also pointed out that some of the cost would be shifted to the Federal Government and would ultimately be borne by taxpayers. A few commenters were concerned this rule would disproportionately increase the financial burden for vulnerable beneficiaries with limited resources that are especially cost-conscious. They stated that premium increases due to the rule may potentially hinder progress in health equity for vulnerable populations and asked CMS to consider the potential to detract from the Agency's overall goal of improving health equity and access.

Response: While reducing overall prices is one of the Administration's objectives, the new definition of ''negotiated price'' set forth in this rule was not intended to meet that objective. The new definition will lead to savings for some beneficiaries by lowering the prices they pay for prescription drugs at the point of sale. As explained in the proposed rule, when pharmacy price concessions and other price concessions are not reflected in the negotiated price (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. A principal purpose of any health insurance is to help reduce the financial burden borne by enrollees who need to utilize covered benefits.[91] We believe it is appropriate that savings from price concessions go toward defraying the out-of-pocket costs of the beneficiaries who purchase prescription drugs.

We disagree that this rule would increase the financial burden for vulnerable beneficiaries, hinder progress in health equity for vulnerable populations, or detract from the Agency's overall goal of improving health equity and access. In fact, the lower cost-sharing for prescription drugs will help beneficiaries with serious health conditions, who bear a disproportionate burden of health care costs. These beneficiaries have reported difficulties paying for prescription drugs as a common problem.[92] As stated earlier in the preamble, the application of all pharmacy price concessions to the negotiated price will lower cost-sharing for beneficiaries with the most serious health conditions. In addition, lower beneficiary cost-sharing can lead to increased medication adherence, which could result in a potential decrease in overall medical costs.[93] Finally, this policy does not change how much LIS-eligible beneficiaries pay in cost-sharing or premiums, and therefore the low-income subsidy will continue to protect the most vulnerable populations.

Comment: A few commenters stated that, although including all pharmacy price concessions in the price at the point of sale could lead to lower cost-sharing for beneficiaries, it does not solve the complexities of drug pricing. For example, these commenters noted that the policy would not help beneficiaries who take expensive drugs with no post-point-of-sale rebates or discounts.

Response: We appreciate the comment. Although we believe adopting this new definition of ''negotiated price'' is an important first step toward improving the affordability of drugs for the majority of beneficiaries who do not receive the low-income subsidy (LIS), and improving price transparency, we acknowledge that this change does not, nor is it intended to, address the full range of complexities of drug pricing, and may not directly reduce out-of-pocket costs for all beneficiaries. However, as discussed in further detail in section IV of this final rule, we project that the new definition of ''negotiated price'' (modified to be applied across all phases of the Part D benefit, including the coverage gap phase (see comments, response and discussion below)) will save beneficiaries $26.5 billion between 2024 and 2032.

Comment: Some commenters opposed the policy on the ground that the new definition of ''negotiated price'' would violate the statutory definition of negotiated price at section 1860D–2(d)(1)(B) of the Act. Some commenters suggested that CMS would be exceeding its delegated authority if it finalized a requirement that all pharmacy price concessions be included in the point-of-sale price. Commenters also stated that Congress's intent was to provide Part D sponsors with the flexibility in administering the Part D prescription drug benefit as a private market model and that the pharmacy price concession rule breaks with this fundamental trust in private markets instilled in the statute by Congress. In addition, some commenters noted that CMS has on multiple previous occasions recognized that the term ''negotiated price,'' as defined by Congress, grants Part D plans discretion in how they treat pharmacy price concessions and, as a result of this flexibility, Part D plans have been drivers of innovation in benefit design. Some commenters contended that CMS cannot now purport to interpret the statute in a way that eliminates post-point-of-sale pharmacy price concessions, given that the agency previously found that the plain language of the statute permitted such price concessions. Further, commenters stated that an agency may not reverse a longstanding and reasoned policy without an adequate and thoughtful explanation for such a decision. Because the rule is unaligned with the intent of Congress, commenters argued, a reviewing court may find such policy changes to be substantively invalid because they would not be based on a permissible construction of the statute.

A few commenters writing in support of revising the definition stated that the statutory definition of negotiated price gives CMS the authority to require Part D plan sponsors to include all price concessions in the negotiated price. These commenters explained that section 1860D–2(d)(1)(B) of the Act specifies that the negotiated price ''shall'' take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs. These commenters stated that the statute's use of the word ''shall'' means that the negotiated price is required to reflect these price concessions. These commenters reasoned that, because the statute does not specify what percentage of these price concessions must be used to lower negotiated prices and thus passed through to patients at the point of sale or otherwise provide details about implementing the pass-through requirement, CMS has the authority to fill in those details. These commenters noted that plan sponsors and PBMs have exploited the ability to exclude price concessions that ''cannot reasonably be determined at the point of sale'' under the current definition of negotiated price. These commenters stated that plan sponsors and PBMs have applied this exception broadly and not passed the vast majority of pharmacy price concessions through to the point of sale, and that by doing so, plan sponsors and PBMs are violating CMS's intent in allowing this exception (see 2014 final rule titled ''Contract Year 2015 Policy and Technical Changes to

[91] Keisler-Starkey, K.B., & Bunch, L.N. (2021). Health Insurance Coverage in the United States: 2020. *United States Census Bureau.*

[92] Kyle, M.A., Blendon, R.J., Benson, J.M., Abrams, M.K., & Schneider, E.C. (2019). Financial hardships of Medicare beneficiaries with serious illness. *Health Affairs, 38*(11), 1801–1806.

[93] Cong, M., Chaisson, J., Cantrell, D., Mohundro, B.L., Carby, M., Ford, M., . . . & Nigam, S.C. (2021). Association of co-pay elimination with medication adherence and total cost. *The American Journal of Managed Care, 27*(6), 249–254. *https://doi.org/10.37765/ajmc.2021.88664.*

the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29878), which appeared in the **Federal Register** on May 23, 2014).

Response: As we stated in the proposed rule, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' The statutory language does not prescribe the extent to which the negotiated prices shall take into account negotiated price concessions, and therefore, provides CMS with the authority to decide whether plan sponsors should be required to include all price concessions in the negotiated price. We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). Although we continue to believe that the prior interpretation of ''take into account'' was permissible, we believe that our initial interpretation may have been overly definitive with respect to the intended meaning of ''take into account.'' Requiring that all pharmacy price concessions be applied at the point-of-sale would ensure that negotiated prices ''take into account'' at least some price concessions and, therefore, would be consistent with and permitted by the plain language of section 1860D–2(d)(1)(B) of the Act. In this way, the negotiated price is required to ''take into account'' these price concessions. This policy we are finalizing is thus consistent with the statutory definition of negotiated price. In addition, the policy we are adopting is consistent with CMS's delegated authority to interpret the statute and administer the Medicare program. Moreover, the statutory definition of negotiated price should be viewed in the broader context of administration of the Part D program and support better functioning of the Part D benefit overall. The policy we are adopting does so by addressing market incentives for plans to keep premiums low, by reducing point-of-sale costs for beneficiaries and by bringing the balance of cost-sharing among the government, plans, and beneficiaries into better alignment. We disagree with commenters who contend that CMS cannot change its interpretation of the statute. As noted above, the statutory language at section 1860D–2(d)(1)(B) of the Act does not prescribe the extent to which the negotiated prices shall take into account negotiated price concessions, and therefore, provides CMS with the authority to decide whether plan sponsors should be required to include all pharmacy price concessions in the negotiated price. We believe that it is a permissible interpretation of the statute to require that all pharmacy price concessions be applied at the point of sale. The policy decision to treat pharmacy price concessions in this way is supported by evidence indicating that very few pharmacy price concessions are being passed on to beneficiaries in the form of lower cost-sharing at the point of sale and the significant growth in such concessions. As noted by some commenters, CMS originally believed that Part D plans would apply price concessions to the negotiated price due to pharmacy and beneficiary market competition; however, this has not been occurring as expected. As discussed in the proposed rule preamble, the sponsor reported data and stakeholder comments (83 FR 62174 through 62180) indicate that most price concessions are being applied after the point-of-sale. We reconsidered our interpretation of section 1860D–2(d)(1)(B) given that the initial interpretation does not accomplish the goals of meaningful price transparency, consistent application of pharmacy payment concessions, and preventing cost shifting to beneficiaries and taxpayers. We also disagree with commenters who claim that CMS is reversing its longstanding policy without an adequate explanation. CMS has carefully and thoroughly considered this issue over several years. Indeed, since 2014, CMS has addressed this topic multiple times, including soliciting comment through a formal process three times and holding numerous listening sessions.

We disagree with commenters who contend that the policy we are adopting in this rule is inconsistent with trust in private markets or would hinder innovation in benefit design. As noted in the proposed rule, this policy changes the reporting requirements for Part D sponsors; it does not govern payment arrangements or eliminate post-point-of-sale price concessions, but rather only requires that all pharmacy price concessions be included in the negotiated price. Therefore, Part D sponsors remain free to negotiate innovative arrangements with network pharmacies. In addition, to the extent our policy increases transparency and information symmetry, as noted previously, it would improve competition in private markets. Regarding comments about Congressional intent for Part D sponsor flexibility, we do not believe this policy fundamentally changes Part D sponsor flexibility in administering the Part D benefit. Sponsors continue to exercise extensive flexibility over plan design and payment.

CMS appreciates commenters support for the revision of the regulatory definition and statutory interpretation. As discussed in the preamble and mentioned by commenters that support revising the definition, this policy requiring that all pharmacy price concessions be applied to the negotiated price would ensure that negotiated prices ''take into account'' *at least some* price concessions and would be passed on to beneficiaries in the form of lower cost-sharing at the point of sale.

Comment: A few commenters stated that a requirement that the negotiated price reflect the lowest possible reimbursement to the pharmacy at the point of sale would violate the statutory prohibition under section 1860D–11(i) of the Act on CMS ''institut[ing] a price structure for the reimbursement of covered part D drugs.'' Commenters stated that requiring pharmacy price concessions to be passed through at the point of sale would effectively create a price structure for pharmacy payment whereby sponsors would have to negotiate only on the lowest possible price/rates with each and every pharmacy with which they contract. Commenters argued that this ''single variable negotiating system'' would result in standard rates across all pharmacy lines of business.

Response: CMS did not propose, and is not adopting, a price structure for the reimbursement of covered Part D drugs; rather, the requirement that the negotiated price reflect the lowest possible reimbursement the pharmacy will receive for a particular drug regulates only the reporting of data on the PDE record. The examples provided in this rule under section 3c. Lowest Possible Reimbursement Example clearly illustrate how the requirement that the negotiated price reflect the lowest possible reimbursement would be reflected on the PDE, under different payment arrangements. The policy we are adopting in this final rule has no bearing on how a pharmacy's payment is calculated or what price structure sponsors use. Sponsors still have the option of negotiating with pharmacies on factors related to the payment rate ultimately received by the pharmacy, which may be higher than the negotiated price. While sponsors must comply with the prompt payment requirements at § 423.530, they continue to have discretion over the timeframes

for settling payment incentives and penalties.

Comment: Most commenters, including beneficiary advocates and beneficiaries, applauded CMS' effort to provide cost-sharing relief to beneficiaries.

Some commenters stated that, if finalized, the requirement that all pharmacy price concessions be included in the negotiated price would increase beneficiary confusion and frustration over health care costs. These commenters suggested that beneficiaries do not have an awareness of the impact of pharmacy price concessions on their overall pharmacy drug and premium costs, and beneficiaries will not understand that their increased premium costs will be due to Part D sponsors no longer reporting pharmacy price concessions as DIR.

Response: We thank commenters for their support of the application of all pharmacy price concessions to the negotiated price, which will lower beneficiary cost-sharing. Moreover, establishing consistency in how sponsors report pharmacy price concessions will allow for more meaningful price comparisons (for both premium and cost-sharing) and more well-informed choices by consumers. While beneficiaries may not immediately understand the factors underlying premiums increases and cost-sharing decreases, they will be better positioned to compare plans, because the standardized reporting of negotiated price required by this rule will create a more consistent basis for comparing plans based on premiums and cost-sharing.

Comment: Several commenters who opposed adopting a new definition of ''negotiated price'' stated that a requirement that all pharmacy price concessions be passed through at the point of sale, as opposed to being reported as DIR, would violate the statutory ''non-interference clause,'' at section 1860D–11(i) of the Act, which specifies that ''the Secretary . . . may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors.'' A few commenters charged that the new definition would be designed to directly affect the contracting processes between plans and pharmacies by mandating changes to point-of-sale prices. Several commenters indicated that the policy would take away Part D sponsors' and PBMs' ability to negotiate downside incentives with pharmacies tied to performance or quality targets, and that it would impair their ability to negotiate rates with pharmacies. A few commenters suggested that the new definition would limit the tools available to Part D sponsors to establish varied and innovative incentive arrangements with contracted pharmacies intended to achieve important goals, such as increasing generic dispensing rates, and to focus on priorities, such as reducing the use of high-risk medications and improving medication adherence. Several commenters asserted that pharmacy price concessions are used to develop a preferred pharmacy network while also keeping Part D premiums low and expressed concern that adopting the new definition of ''negotiated price'' would limit the ability of plan sponsors to negotiate effective, high-value contracts with pharmacies, resulting in an increase in both beneficiary premiums and government spending, as well as a decrease in preferred pharmacy networks.

A commenter noted that this policy would adversely affect the reductions in cost-sharing for beneficiaries that have been realized under the Part D Senior Savings Model. The commenter stated that Part D plans that participate in this Center for Medicare & Medicaid Innovation (CMMI) model are relying on their preferred pharmacy networks to stock and dispense specific products. The commenter noted that additional contract terms help plans achieve goals under models and that pharmacy interactions can increase adherence to prescribed medications and foster therapeutic substitution that can save beneficiaries and plans money in the long run. The commenter stated this policy will put the benefits achieved through this model at risk by interfering with the relationships that have been formed between PBMs and pharmacies.

Some commenters stated that the new definition of ''negotiated price'' would not violate the ''non-interference clause.'' Several commenters asserted that CMS would not be inserting itself into negotiations between plan sponsors, PBMs, and pharmacies by defining the negotiated price and altering the manner in which to account for pharmacy price concessions. Rather, some commenters stated, CMS is authorized to promulgate regulations in accordance with the Medicare statute's any willing provider and prompt payment requirements, and such regulations would not run afoul of Medicare's non-interference clause. Commenters also noted that CMS retains authority to promulgate such regulations in the interest of protecting market competition, which is consistent with the plain meaning of the text of the non-interference clause. Some commenters noted that plan sponsors and their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or pay structure they like.

Response: We agree with commenters that this rule does not violate the non-interference clause. This rule does not implicate or impose requirements on plan-pharmacy interactions, such as contracting, negotiations, payments rates, incentive arrangements, quality goals or targets, performance-based payments or performance-based contracting. Sponsors and pharmacies remain free to negotiate any such arrangements they wish—this rule requires only that the negotiated price reflect the price that the parties have negotiated as the lowest possible reimbursement that the pharmacy could receive for a particular drug, inclusive of all pharmacy price concessions. As noted above, the requirement that the negotiated price reflect the lowest possible reimbursement that a pharmacy receives for a drug is directly related to the reporting of data on the PDE record and determination of beneficiary cost-sharing and to promoting price transparency to the beneficiary. The connection that commenters make between this policy and adverse effects on the Part D Senior Savings model and Part D sponsors and pharmacy relationships is unclear. To the extent that our policy has an effect on the calculation of cost-sharing under the model, we would anticipate that the model could be adapted, to accommodate new requirements and policies. As we have stated previously, this policy does not impose requirements on contracts between sponsors or their PBMs and pharmacies; therefore, we do not see how this policy affects performance-based payment adjustments that exist in the Senior Savings Model. We agree that pharmacy interactions can increase adherence to prescribed medications and foster therapeutic substitution that can save beneficiaries and plans money in the long run.

Comment: A commenter noted that beneficiary costs are based on a combination of premiums and cost-sharing, both of which are already fully disclosed to the beneficiary through plan materials and other tools like Medicare Plan Finder (MPF). This commenter stated that beneficiaries use tools like MPF to choose plans based on factors including cost-sharing, premiums, formulary coverage, pharmacy network, Star Ratings, and integration or non-integration with MA plans. This commenter maintained that tools like MPF already allow for a real, meaningful, and actionable comparison of plan prices and efficiencies and

therefore, promoting transparency through this policy is unnecessary.

Commenters believed that the pharmacy price concession rule will undo the effectiveness of MPF and create less transparency by causing confusion with the introduction of the new definition of negotiated price. Commenters were also concerned that if CMS allows plans the flexibility to determine how much of the pharmacy price concessions to pass through at the point of service (POS) for applicable drugs in the coverage gap (while using the negotiated price determined using the lowest possible reimbursement to the pharmacy in the non-coverage gap phases), then MPF will need to be updated to account for the differences, which could add to beneficiary confusion.

Commenters recommend that CMS use the MPF tool to examine which factors most impact beneficiaries when making a plan choice before CMS makes drastic changes to the program through the pharmacy price concession rule. They suggested that CMS use underlying MPF data to perform analysis to determine how important premiums are in the total calculus of plan choice as compared to overall out-of-pocket (OOP) costs.

Commenters also stated that the proposal would require development of processes to ensure accurate information is posted on MPF and that there would be considerable challenges with loading accurate pharmacy network data into MPF in a timely fashion, as there is likely to be increased network volatility as contracts are renegotiated.

Response: We agree with commenters that MPF is a valuable tool that beneficiaries use to make informed decisions. We note that the cost-sharing and premium data for Part D reflected in the MPF is and will continue to give beneficiaries an accurate assessment of their expected costs for a given plan. This policy does not affect the accuracy of the data in MPF as the new definition of negotiated price does not change how the out-of-pocket costs are displayed to the beneficiary. As discussed elsewhere in this rule, CMS is finalizing a policy to require that pharmacy price concessions be applied to the negotiated price across all phases of the Part D benefit, including the coverage gap phase. Therefore, MPF will not need to account for the difference in how pharmacy price concessions are applied in the gap verses non-coverage gap phases. Thus, we do not see how commenters' claims that the new definition will cause confusion due the new definition of negotiated price are substantiated.

In addition, CMS's MPF tool utilizes drug prices net of rebates and other price concessions that are applied at the point of sale, so MPF's current design already supports the collection and display of drug prices as contemplated under this rule. Therefore, CMS does not anticipate implementing changes to the MPF tool or the methodology currently in place. Plans should refer back to the Part D drug pricing submission guidance published annually by CMS. This guidance provides technical instructions on how to submit drug prices that account for rebates and other price concessions that are applied at the point of sale. The applicability date of January 1, 2024, for the new definition of negotiated price provides time for sponsors to prepare data for submission to MPF.

We understand that beneficiaries consider many factors in selecting a plan and that the relative importance of premium costs as opposed to out-of-pocket costs can vary depending upon a beneficiary's particular circumstances. Moreover, even for beneficiaries who prioritize premium costs over other factors, this rule will result in premiums that better reflect the relative efficiency of plan designs for prescription drug coverage, and therefore, this policy will contribute to more informed choices by beneficiaries.

Comment: A few commenters expressed concern that the impact of the rule would likely be more profound on prescription drug plans (PDPs) than Medicare Advantage prescription drug (MA–PDs) plans, as many PDPs would be unable to avoid a significant increase in premiums, and could potentially be priced out of the market. Commenters explained that PDPs lack the additional financial cushion available to MA organizations (MAOs) as a result of their offering an integrated benefit. Also, PDPs lack the financial incentives of Star Ratings bonus payments for which MAOs are eligible. Commenters were concerned that as beneficiaries lose access to PDPs, many would be forced to enroll in MA–PDs, and be driven from original Medicare, which may be a source of comfort and stability to many, especially older beneficiaries, into managed care plans.

Response: CMS appreciates the comments and concerns about potential differential impacts on PDPs versus MA–PDs. One outcome of this rule is that beneficiary cost-sharing may be reduced, regardless of the plan type in which they are enrolled. The statement that beneficiaries may be driven from original Medicare to Medicare Advantage assumes that Part D benefits are the sole factor behind individuals' decisions in choosing between original Medicare and Medicare Advantage. We note that many factors, such as geographic location, Medicare Advantage plan options, and preferences related to provider choices, are also important considerations for many beneficiaries in choosing between original Medicare and Medicare Advantage. We also note that beneficiaries selecting original Medicare (for other reasons) will be comparing PDP premiums against one another and not comparing PDP premiums against MA–PD premiums. Medicare Advantage plans that use Part C rebates to offset Part D premium increases may need to forgo offering other benefits that would have been provided with those funds.

Comment: Some commenters stated that it would be extremely challenging, if not impossible, to implement changes to bid assumptions, renegotiate pharmacy contracts, and make the necessary revisions to pharmacy adjudication systems prior to January 1, 2023, and recommended that the implementation of the rule be postponed until 2024 or later. Commenters noted that if the rule is applicable for contract year 2023, there could be disruptions in member benefits because of the contracting and systems changes that would have to happen in time for the Fall 2022 Open Enrollment. As a result of the compressed timeline, they are concerned that focus will be taken away from member benefits.

A commenter noted that Part D plan sponsors would need to renegotiate their contracts with PBMs. This commenter stated that not only would it be necessary to renegotiate fee arrangements, but also, given the rule, Part D plan sponsors may want to discuss new business strategies and underwriting scenarios with their PBMs. The commenter explained that this is a lengthy, resource-intensive process that precedes pharmacy contracting because it is the plan that sets the target for pharmacy contracts that the PBM negotiates. This commenter stated that CMS' proposed timeline would cause the Part D sponsor/PBM negotiations to occur at the same time as PBMs are trying to renegotiate pharmacy contracts.

Commenters also explained that changes to pharmacy contracts would not be mere technical changes, but would include how, when, and the amount pharmacies would receive in reimbursement. Commenters stated that most pharmacies are likely to see a significant reduction in reimbursement, which could result in some pharmacies

refusing to participate in the Part D network at the new reimbursement rate. Commenters explained that issues with participation could impact preferred pharmacy arrangements and network access, which could result in additional time needed for additional contracting to ensure that pharmacy network access requirements are satisfied.

However, other commenters indicated that plans/PBMs customarily impose new terms without any consultation or negotiation. Some commenters stated that most fees charged to pharmacies are placed in the provider manual, which is included by reference into the contract terms. A commenter stated that all or substantially all PBMs have contractual terms in place with pharmacies to enable payment term modifications for any change in DIR, such as requiring immediate renegotiation of rates or setting a fixed reimbursement rate in the event of policy change. This commenter believed that any additional delay in providing this rule would improperly place Part D plan sponsor and PBM profits above beneficiary well-being and believe CMS' current proposed timeline is appropriate.

Response: We find commenters' concerns regarding the ability to effectuate contract negotiations and make potential systems changes in time for 2023 implementation to be compelling. To give all parties sufficient time to implement this policy, including making the systems changes that will be needed to ensure that cost-sharing is correctly adjudicated for beneficiaries at the point of sale, we are modifying our proposal and finalizing an applicability date of January 1, 2024. This will give the Part D sponsors over a year to contract and prepare bids for the 2024 contract year. In addition, based upon our experience implementing changes in the Part D program that require Part D sponsor and PBM system changes, we believe that this additional time is sufficient to operationalize the new definition of negotiated price. We are making corresponding changes to the regulation at 42 CFR 423.100 to retain the current regulatory definition of ''negotiated prices'' for 2023 and adopt the new regulatory definition of ''negotiated price'' for 2024 and thereafter.

Comment: A significant volume of letters were submitted as the result of a letter writing campaign and encouraged CMS to move forward as swiftly as possible in adopting the new definition of negotiated price.

Response: We thank the commenters for their feedback. While we appreciate the need to pass meaningful out of pocket cost savings to and increase drug price transparency for beneficiaries as soon as possible, concerns related to contracting and operational timelines that could disrupt successful implementation are sufficiently compelling to warrant making this policy applicable beginning on January 1, 2024.

After consideration of comments received, CMS is finalizing the new definition of negotiated price at § 423.100 effective January 1, 2024. Under this definition, the negotiated price must be the lowest possible reimbursement a network entity will receive, in total, for a particular drug and include all pharmacy price concessions. To implement this policy, we will also remove the existing definition of negotiated prices at § 423.100, effective January 1, 2024.

b. Lowest Possible Reimbursement

To effectively capture all pharmacy price concessions at the point-of-sale consistently across sponsors, we proposed to require that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest possible reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR as part of the annual report on DIR following the end of the year. For an illustration of how negotiated prices would be reported under such an approach, see the lowest cost reimbursement example provided later in this rule.

By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. The proposed rule discussed our bases for believing that requiring that the negotiated price reflect the lowest possible reimbursement a network pharmacy could receive for a Part D drug is the best approach to achieve our goals, as noted previously, of (1) consistency (standardized reporting of negotiated prices and DIR); (2) preventing cost-shifting to beneficiaries; and (3) price transparency for beneficiaries, the government, and other stakeholders.

Consistent with this approach, we proposed that all contingent incentive payments (that is, an amount that is paid to the pharmacy instead of a price concession from the pharmacy) be excluded from the negotiated price. As explained in the proposed rule, including the amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty, and would also reduce price transparency. This pricing differential could create a perverse incentive for beneficiaries to choose a ''lower performing'' pharmacy for the advantage of a lower price. Additionally, Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition as proposed would mitigate this concern by allowing sponsors and their intermediaries to continue to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per claim. Further, we emphasized that the proposed changes would not require pharmacies to be paid in a certain way; rather we would be requiring standardized reporting to CMS of drug prices at the point of sale.

c. Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under our proposal, we provided the following example. Suppose that under a performance-based payment arrangement between a Part D sponsor and its network pharmacy, the sponsor will implement one of three scenarios: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy $100 at the point-of-sale, the pharmacy's final reimbursement under this arrangement would be: (1) $95 for poor performance; (2) $100 for average performance; or (3) $101 for high performance. Under the current definition of negotiated prices, the reported negotiated price is likely to be $100, given the reasonably determined exception for contingent pharmacy payment adjustments. However, under the proposed definition, for all three performance scenarios, the negotiated price reported to CMS on the PDE record at the point of sale for this drug would be $95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100). Finally, any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. Under this requirement, the sponsor would report $0 as DIR under the poor performance scenario ($95 minus $95), −$5 as DIR under the average performance scenario ($95 minus $100), and −$6 as DIR under the high-performance scenario ($95 minus $101), for every covered claim for this drug purchased at this pharmacy.

Comment: Many commenters encouraged CMS to address the proposed rule's potential impact on pharmacy cash flow during the first quarter of 2023 assuming the rule is implemented in January 2023. Many commenters expressed concern that a pharmacy's payments for CY 2022 DIR fees to Part D sponsors and/or their PBMs will be due concurrently with the time pharmacies expect to receive lower reimbursements at the point of sale. Many of these commenters urged CMS to implement this proposal on January 1, 2023; however, due to the potential impact of the retroactive fees and implementation of the rule, these commenters urged CMS to require sponsors and/or their PBMs to establish payment plans with pharmacies that need them during the transition period. Commenters noted that when Medicare Part D was established, hundreds of pharmacies closed because of cash flow issues, necessitating Congressional action to establish prompt pay rules. These commenters urged that CMS emphasize that prompt payment requirements will continue to be enforced.

Response: CMS understands these concerns but does not have the authority to mandate payment plans between plans sponsors and pharmacies. We acknowledge the possibility that changes in cash flow may cause some already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks. Note that CMS will be particularly attuned to plan compliance with pharmacy access standards under § 423.120 to ensure that all Medicare Part D beneficiaries have convenient access to pharmacies and medications. Therefore, we encourage Part D sponsors to consider options, such as payment plans or alternate payment arrangements, to minimize impacts to vulnerable pharmacies and the patients they serve. We also note that the prompt payment requirements for Part D, as described in § 423.520, will continue to apply and that Part D sponsors must pay clean claims in accordance with the prompt pay regulation. As noted elsewhere, we are finalizing an applicability date of January 1, 2024, instead of January 1, 2023. Nonetheless, we would expect these same concerns that commenters raised for January 1, 2023 to be similarly applicable to January 1, 2024. With this extra implementation time, we believe Part D sponsors and pharmacies will now have adequate time to implement payment plans or make other arrangements to address these cash flow concerns at the beginning of 2024.

Comment: Many commenters wrote in support of a requirement that the negotiated price reflect the lowest possible reimbursement to the pharmacy because they believed this approach would make it possible for pharmacies to better predict the minimum reimbursement they could receive on a per-claim level.

Response: We thank these commenters for their support of this policy. We agree that defining negotiated price to mean the lowest possible reimbursement received by the pharmacy will provide greater transparency and may improve predictability of per-claim revenue.

Comment: Several commenters opposed the policy, suggesting that a requirement that the price paid to a pharmacy for a covered Part D drug be net of all possible downward adjustments would effectively eliminate the ability of Part D plans to employ performance-based negative pharmacy payment adjustments. A few commenters suggested that the elimination or restriction of performance-based pharmacy payment arrangements is out of line with current CMS initiatives to expand and incentivize value-based arrangements, such as the recently announced agenda to expand value-based care in Medicare by CY 2023. Commenters stated that restricting or eliminating payment arrangements that incentivize pharmacy performance is counterintuitive to these ongoing efforts to bring increased value to the Part D program as well as the rest of Medicare. A few commenters stated that this rule will make it harder to achieve the bold quality agenda set forth by CMS (cited in *Health Affairs* written by CMS officials). These commenters stated that pharmacy DIR is generated by two-sided, value-based contracts—similar to contracts entered into by health plans and other providers as the optimal path to transform health care delivery and payment. These commenters also noted that these pharmacy DIR contracts often focus on driving Stars performance and increasing generic dispensing to the benefit of the Medicare program and its beneficiaries. Some commenters stated that applying all pharmacy price concessions at the point of sale would negatively impact Star Ratings and performance-based models such as MIPS and APMs. Commenters argued that if sponsors adopt a ''bonus only model'' when paying pharmacies for performance, there will not be an adequate financial incentive for pharmacies to help plans improve pharmacy measures. A few commenters noted that performance on adherence measures has been trending up as has the generic dispensing rate and MTM completion. These commenters stated that this proposal would interfere with the DIR contracting that has yielded these impressive results.

A commenter noted that recent research has shown that pharmacy performance measures that address social determinants of health (SDOH) help promote equitable and high-quality care. The commenter stated that Medicare beneficiaries are best served when their providers are focused on addressing community-level SDOH barriers, and in pharmacy care, a number of programs are funded and incentivized through Part D plan price concessions that CMS would effectively eliminate.

Response: We did not propose to eliminate or restrict the use of any performance-based pharmacy payment arrangements, and we do not agree that a policy of requiring the negotiated price to reflect the lowest possible reimbursement to the pharmacy for a Part D drug eliminates or restricts Part D sponsors' ability to institute performance-based pharmacy payment arrangements. The new definition of negotiated price that we are adopting in this final rule does not mandate how sponsors contract with, incentivize, or pay pharmacies in their network. The new definition of negotiated price applies only to how the PDE data is populated and reported and thus the price of the drug on which beneficiary cost-sharing is determined. We also disagree with the implication that performance-based contingent incentive payments provide pharmacies with insufficient motivation to engage in activities that impact sponsors' Star Ratings and other performance-based models. Rather, sponsors remain free to motivate pharmacies by offering performance-based payment arrangements to pharmacies. Applying all pharmacy price concessions to the negotiated price will provide pharmacies with more information on the reimbursement they will receive if they fail to meet performance metrics. While we are not specifying payment arrangements between plan sponsors and pharmacies, we encourage fair and equitable value-based arrangements, including those focused on social determinants of health (SDOH), that improve beneficiaries' quality of care and reduce health care costs.

Comment: Many commenters urged CMS to collect pharmacy performance measure information from Part D sponsors as finalized in the January 2021 final rule (86 FR 5864) to assess concerns raised by pharmacies about performance measures. Several commenters noted that PBMs often apply one-size-fits-all metrics that are not relevant to a pharmacy's population or specialty. Commenters explained that they are penalized for not having a large enough population for a credible sample that PBMs use to assess performance. A few commenters noted they were penalized for not meeting generic dispensing rates because the pharmacies are specialty pharmacies serving a population whose medical conditions do not have available generic drugs for treatment. A commenter recommended that plan sponsors not be able to apply the pharmacy price concessions to all pharmacies within a particular chain of pharmacies, such as local chains or supermarket pharmacies, based on the performance of the lowest performing pharmacy in the chain. This commenter stated that the ability of pharmacies to meet performance standards set forth by PBMs and plan sponsors is hindered by the fact that no consideration is given to inherent handicaps, such as socio-economic disparities between pharmacy geographic locations or as noted above differences in dispensing practices between retail and specialty drugs. Many commenters noted that penalties from one measure and one medication are applied to all medications, setting thresholds pharmacies cannot meet.

Response: We appreciate the comments regarding the nature of and differing application of pharmacy performance metrics to assess pharmacy performance; however, we did not propose to address pharmacy performance metrics in the proposed rule. We addressed reporting of pharmacy performance measures to CMS in the January 2021 final rule (86 FR 5864). In the January 2021 final rule, we finalized a proposal to give CMS the authority to establish a Part D reporting requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. This authority to establish a reporting requirement is effective January 2022; however, the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package. We encourage the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We are aware that the Pharmacy Quality Alliance (PQA), a measure developer, is working to build consensus on pharmacy-level measures across pharmacies, plans, PBMs, and other stakeholders.

Comment: Some commenters stated that CMS did not articulate any rational basis for giving ''preferable'' treatment for pharmacy incentive payments over pharmacy price concessions. A few commenters asserted that giving special treatment to higher payments to pharmacies underscores the arbitrary and capricious nature of CMS's effort to redefine negotiated price. A few commenters supported a requirement that all contingent incentive payments be excluded from the negotiated price. The commenters noted that this approach supports PBMs' ability to measure and monitor pharmacy performance on Stars Ratings-related measures and incentivize pharmacies for their performance without negatively impacting the beneficiaries' cost-sharing.

Response: We disagree that the proposal gives preferential treatment or higher payments to pharmacies. The proposed rule does not impose requirements on the actual payments made to pharmacies. This rule sets forth requirements that standardize how and when pharmacy price concessions are reported to CMS. In the proposed rule, we described the information gathered through the Request for Information in the November 2017 proposed rule regarding pharmacy price concessions (payments from network pharmacies to sponsors or their intermediaries for ''poor performance'') and incentive payments (payments made to pharmacies by plan sponsors or their intermediaries for ''high performance''). The primary concern with including incentive payments in the negotiated price is that including these types of payments in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty. This pricing differential could create a perverse incentive for beneficiaries to choose a ''lower performing'' pharmacy for the advantage of a lower price. Additionally, Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition to include pharmacy price concessions and not incentive payments would mitigate this concern by allowing sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per

claim. We thank the commenters for the support on excluding incentive payments from the negotiated price and agree that not including contingent incentive payments in the negotiated price best aligns beneficiary, plan, and pharmacy incentives.

Comment: Many commenters requested that CMS establish safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement. These commenters urged the administration to ensure that the negotiated price at a minimum cover the pharmacy's costs of purchasing and dispensing covered items and providing covered services. A few commenters requested that CMS establish a flat dispensing fee or an alternative model such as a pharmacy reimbursement model based on a public drug pricing benchmark such as national average drug acquisition costs (NADAC) plus a fair dispensing fee in line with those in state Medicaid fee-for-service program.

Response: Thank you for these suggestions. CMS will consider these suggestions for future rulemaking.

Comment: Some commenters suggested that, as an alternative to requiring that all pharmacy price concessions be included in the negotiated price, CMS could achieve the policy goals of controlling and reducing drug prices and improving transparency by making changes to the treatment of pharmacy DIR in Part D sponsors' bids. Some commenters recommended that plan sponsors be required to reflect some or all of the expected pharmacy DIR in cost-sharing amounts when they submit their Part D bids. A few commenters encouraged CMS to consider imposing a penalty for systematically underestimating DIR within plan bids.

Some commenters offered alternatives to the implementation of the new definition of negotiated price. One suggestion was to offer Part D sponsors the flexibility to launch an additional new plan beyond what is currently allowable, for example, three PDP products per contract. This new plan could be structured to test CMS' negotiated price proposal, while the other existing Part D plans remain using the current approach. A similar suggestion was for CMS to perform a case-control study to test the implementation of the new definition of negotiated price. A third suggestion was for CMS to require additional options for treatment of pharmacy price concessions. These options could for example, include no pharmacy price concession arrangements or explicitly limit the amount of pharmacy price concession payment arrangements relative to point-of-sale payments. Under this approach, pharmacies could choose one of the options and not be excluded from network participation. Commenters noted that these approaches would allow CMS to gather data before finalizing the requirements set forth in this rule.

A few commenters recommended that CMS focus on creating pricing transparency through the widespread use of provider and beneficiary-level real-time benefit tools (RTBT). One of these commenters explained that prescriber RTBT allows for real-time decision-making to guide beneficiaries, advise them of their options with a focus on clinically needed drugs and the prices of those drugs. According to the commenter, although many plans use RTBT, the tools are proprietary and can lead to highly variant experiences. Congress has mandated broader adoption of RTBT by 2023 and mandated provider use of these tools. The commenter noted that National Council for Prescription Drug Programs (NCPDP) has developed a standard for a real-time prescription benefit request and response for use by providers and asked that CMS name the specific telecommunications standard for use by Part D program participants. This commenter believes that RTBT, rather than changing point-of-sale pricing, creates a way to get pricing information into the hands of beneficiaries, without the need for computers or smart phones, which promotes efficient and socially sensitive SDOH-focused care delivery.

Response: We thank commenters for their suggestions regarding alternative approaches to implementing the new definition of negotiated price, but we decline to adopt these approaches. We do not believe that a policy that requires sponsors to include all pharmacy price concessions in the negotiated price and some of the alternatives suggested by commenters are mutually exclusive or that the availability of alternatives should prevent us from adopting the revised definition of ''negotiated price.''

With regard to use of the RTBT to promote price transparency, CMS is committed to the use of tools that promote efficient and socially sensitive social determinants of health focused care delivery. Regulations at § 423.160(b)(7) require Part D plans to implement one or more electronic RTBT capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR). CMS will continue to evaluate available electronic standards for RTBT to determine if they are appropriate for the Part D program and propose updated standards, if appropriate. In the meantime, this rule will promote lower beneficiary cost-sharing, which also will help beneficiaries to overcome financial barriers to the medications they need.

Comment: A few commenters recommended that if CMS instructs plans to bid with existing law and regulations in effect currently for the 2023 bid deadline and then finalizes this policy as proposed, then CMS consider conducting the proposed 2019 voluntary two-year demonstration that would consist of a modification to the Part D risk corridors in order to better manage a transition to new requirements.

Response: Thank you for the suggestions. However, we decline to adopt them at this time, as we have changed the applicability of this rule to January 1, 2024, which, as noted previously, provides sufficient transition time.

After considering the comments received, we are adopting a requirement as proposed that the negotiated price reflect the lowest possible reimbursement that the network entity will receive, in total, for a particular covered Part D drug, including all price concessions and any dispensing fees, but excluding additional contingent amounts that increase prices.

d. Additional Considerations

In order to implement the proposed change, we indicated we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point of sale. Specifically, we indicated we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect the amount of point-of-sale pharmacy price concessions. We also indicated that we would likely use fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession data at the plan and national drug code (NDC) levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year.

Comment: Several commenters questioned how data ensuring the lowest possible reimbursement will be transmitted to the pharmacy via the required HIPAA-standard transactions and how data will map to the PDE and to the pharmacy remittance. Both plan/PBMs and pharmacies raised these questions, as all stakeholders are currently required to use the National Program for Prescription Drug Plans (NCPDP) Telecommunications standard

version D.0 (D.0) for claims adjudication, and the Health Care Claim Payment/Advice Transaction Set (X12 835) to support the claims payment process. A few commenters stated that D.0 would need to be replaced by an updated standard, as the current standard cannot support another cost field to convey post-point-of-sale remuneration to downstream entities. A commenter posited that such capability would not be available until 2027 or beyond.

Response: We disagree with commenters that there is no mechanism under the current NCPDP data format for Part D sponsors to provide information on a drug's negotiated price to pharmacies. PCMS does not dictate or provide guidance regarding plans' billing arrangements, and has identified the two following approaches that could accomplish the goal of transmitting a drug's negotiated price data between plan sponsors and pharmacies using the data format available today.

The following example reflects a payment arrangement where the pharmacy point-of-sale payment reflects the negotiated price.

Example 1: Pharmacy is paid Negotiated Price of $90 at the Point of Sale.

Pharmacy Point-of-Sale Transactions:

- Ingredient Cost Paid + Dispense Fee Paid = $90 (this is the total amount that will be paid to the pharmacy by all parties)
- Patient Pay (beneficiary cost share in deductible is 100%) = $90
- Total Amount Paid (Plan paid) = $0

Because the Negotiated Price of $90 is the lowest possible reimbursement there is no need for an informational field to indicate future deductions from the pharmacy.

The second example reflects a payment arrangement in which a plan/PBM pays the pharmacy more than the negotiated price at the point of sale. The Total Gross Payment (negotiated price plus post-POS pharmacy price concession) could be populated in the Total Amount Paid Field on the claim response, and the post-POS pharmacy could be included in an informational structured text field. Under this scenario the pharmacy could compute the negotiated price by reducing the Total Gross Payment by the amount noted in the informational field on the pharmacy claim response. The PBM would calculate the beneficiary cost share at the point of sale using the negotiated price and not the total gross payment.

The following example reflects this payment arrangement where the price paid to the pharmacy at the point of sale does not reflect the negotiated price and so the amount that needs to be adjusted has to be separately conveyed in the informational field within D.0. The PBM computes beneficiary and plan cost-sharing based on the negotiated price; however, the pharmacy will have to subtract the amount reported by the PBM in the informational field to determine the negotiated price.

Example 2: Pharmacy is paid $100 at the Point of Sale, Negotiated Price is $90.

Pharmacy Point-of-Sale Transactions:

- Ingredient Cost Paid + Dispense Fee Paid = $100 (this is the total amount that will be paid to the pharmacy by all parties)
- Patient Pay (Beneficiary cost share in deductible is 100% of negotiated price) = $90
- Total Amount Paid (plan paid) = $10 (this plan paid amount is necessary to have pricing fields balance on a claim)
- Additional Message Information − (informational structured claim response indicates the amount that could be taken back post point of sale) = Negative $10

Both of these arrangements can be reflected within the current standard, and indeed historically this is how coordination of benefits occurred prior to availability of specific pricing fields. Additionally, any amount paid by the pharmacy to the plan post-point-of-sale could be reported at the claim level (CLP) on the 835 and will be reported in the Estimated Rebate at the Point of Sale field 40 on the PDE as some plans are doing today. This would allow the information to be transparent from the point-of-sale transaction to the PDE.

We agree with commenters who pointed out that the pharmacy price concessions cannot be conveyed to downstream supplemental payers unless price concession values are conveyed in a dedicated cost field, which is not available under D.0. Because these price concession amounts could only be conveyed in an informational field, the current NCPDP standard does not support providing this information to a supplemental payer on a COB claim. So, if the PBM uses the method illustrated in Example 2, the pharmacy would be unable to provide transparency around any amounts that will be taken back post point of sale on the COB claim that will be sent to a supplemental payer. However, we are including Example 2 for PBMs to use when implementing the new rule because it will still benefit those supplemental payers who provide coverage based on beneficiary cost-sharing, and will retain the status quo for supplemental payers who pay based on plan-paid amounts.

Comment: A few commenters explained that Part D bidding and payment policies in the Advance Notice would be impacted by these provisions that are not mentioned in the AN. For example, the risk adjustment model for CY 2023 is proposed to be calibrated on 2018 claims and encounter data, plus expenditure data from 2019 PDE records that do not reflect pharmacy DIR being applied at POS. Commenters noted that the risk adjustment is not the only issue impacted by pharmacy DIR at POS but also the underlying trends used to make the annual adjustments to Medicare Part D benefit parameters would also be impacted.

Response: Given that we are finalizing an applicability date of January 1, 2024, the policy we are adopting will not affect Part D payment in 2023. We will consider commenters' feedback as we prepare the Part D payment policies for the 2024 Advance Notice.

Comment: A few commenters urged CMS' Office of the Actuary to provide plan sponsors with bid guidance as soon as possible to ensure accuracy of the bids. Commenters noted that the pharmacy DIR impacts if the rule were final, were not referenced in the draft Bid Pricing Tool (BPT) or the Advance Notice. Commenters noted that Part D sponsors will have to choose whether to prepare their bids under current regulations where they assume that (a) the definition of negotiated price remains the same, or (b) the new definition of negotiated price is finalized. A few commenters indicated that if the industry is not aligned on assumptions, there will be significant disruption for beneficiaries due to the erratic bidding in the market. Also, commenters noted that the uncertainty of the proposed rule adds additional actuarial risk, which may result in plans adopting more conservative (that is, higher) plan pricing, in order to mitigate the impacts of the uncertainty during the bidding period.

Response: As noted above, we are finalizing this rule with an applicability date of January 1, 2024. CMS will communicate bid guidance to support the bid development process with sufficient lead time for the 2024 bid cycle.

Comment: A commenter noted that the Out-of-Pocket Cost (OOPC) Models are under development and targeted for release in April 2022, possibly prior to the publication of the final rule. The commenter was concerned as the values produced from these models are used in CMS's bid review and while the

baselines were released on January 21, 2022, the average price for each RxCUI in the model could be influenced by adoption of the proposal to require the negotiated price to include pharmacy price concessions. The commenter stated that CMS would have to decide whether adjustments for potential changes in the average price for each RxCUI in the model would be appropriate. The same commenter noted that in relation to pricing changes, the Health Plan Management System (HPMS) Formulary Submission and Part D Pricing File Submission (PDPFS) Modules are expected to be released on May 16, 2022, and that the formulary submission module may be directly impacted by this proposal, while plan sponsor and PBM formulary strategy most certainly will. The commenter noted that the Part D pricing file module would likely either have to be delayed or re-released to appropriately reflect this final rule.

Response: Given the applicability date of January 1, 2024, changes to the OOPC model tool for 2023 are not needed. We will consider whether updates will be appropriate for the OOPC model for 2024.

Comment: A commenter requested that CMS ensure that Part D sponsors and their PBMs load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. The commenter noted that this information goes hand-in-hand with a real-time prescription benefit model in providing at the point of prescribing and even at the point of dispensing an accurate accounting of the beneficiary's out-of-pocket cost for their prescription.

Response: We appreciate the suggestion. We will monitor the situation to determine whether it is necessary that we take any additional steps to ensure that Part D sponsors and their PBMs have made the appropriate changes to their claims processing systems.

After consideration of the comments, we will finalize our proposal to use existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions to the negotiated price.

e. Negotiated Prices of Applicable Drugs in the Coverage Gap

The negotiated price of an applicable drug is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Section 1860D–14A(g)(6) of the Act provides that, for purposes of the coverage gap discount program, the term ''negotiated price'' has the meaning it was given in § 423.100 as in effect as of the enactment of section 3301 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (PPACA), as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), except that it excludes any dispensing fee for the applicable drug. Under that definition, which is codified in the coverage gap discount program regulations at § 423.2305, the negotiated price is the amount the Part D sponsor (or its intermediary) and the network dispensing pharmacy (or other network dispensing provider) have negotiated as the amount such a network entity will receive, in total, for a covered Part D drug, reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale, and net of any dispensing fee or vaccine administration fee for the applicable drug.

In the November 2018 proposed rule (83 FR 62179), we solicited comment on whether to require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap. Under such an approach, the negotiated price of the applicable drug for purposes of determining manufacturer coverage gap discounts, would include all pharmacy price concessions as in all other phases of the Part D benefit under the proposed revision to the definition of negotiated price at § 423.100. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has *elected* to pass through at the point-of-sale, we explained that we did not believe it would be appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we indicated our belief that there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular applicable drug. We also noted that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor were required to include all pharmacy price concessions in the negotiated price of an applicable drug at the point of sale, the plan sponsor must still make an election as to how much of the overall price concessions (including non-pharmacy price concessions) it receives will be passed through at the point of sale.

In the November 2018 proposed rule, we also sought comment on an alternative approach under which Part D sponsors would determine how much of pharmacy price concessions to pass through at the point-of-sale for applicable drugs in the coverage gap, and beneficiary, plan, and manufacturer liability would be calculated using this alternate definition of negotiated price.

The majority of the comments on the November 2018 proposed rule that addressed the possible inclusion of pharmacy price concessions in the negotiated price of applicable drugs in the coverage gap expressed support for applying the same definition of negotiated price in all phases of the Part D benefit, as they believed maintaining the same definition for all phases of the benefit would provide more transparency and consistency at the point of sale, minimize beneficiary confusion, and avoid the operational challenges of having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit. Some commenters disagreed with our assessment that CMS has the legal authority to require that all pharmacy price concessions be included in the negotiated price of applicable drugs in the coverage gap, as they felt this was at odds with the reference to ''price concessions that the Part D sponsor had elected to pass-through to Part D enrollees at the point-of-sale'' in the regulatory definition of ''negotiated price'' at § 423.100 as in effect when the PPACA was enacted. Commenters noted that if CMS were to adopt the alternative approach under which sponsors would be required to include pharmacy price concessions in the negotiated price for applicable drugs in all phases of the Part D benefit other than the coverage gap, it would be necessary for CMS to issue very specific guidance explaining how to operationalize different definitions of ''negotiated price'' for the coverage gap versus the non-coverage gap phases of the Part D benefit.

In the proposed rule, we noted that we continue to believe that section 1860D–14A(g)(6) of the Act would not preclude us from revising the definition of negotiated price at § 423.2305 to require Part D sponsors to apply all pharmacy price concessions for applicable drugs at the point of sale. However, we did not propose to adopt such a mandate and noted that allowing plans flexibility with respect to the

treatment of pharmacy price concessions for applicable drugs in the coverage gap would moderate increases to beneficiary premiums and government costs.

In summary, under our proposed approach, for non-applicable drugs in the coverage gap, and during the non-coverage gap phases of the Part D benefit for applicable drugs, claims would be adjudicated using the negotiated price determined using the lowest possible reimbursement to the pharmacy. In contrast, for applicable drugs during the coverage gap, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price.

Based on comments we received on the November 2018 proposed rule, we anticipate that if we were to adopt the proposed approach, we would need to provide technical or operational guidance to Part D sponsors regarding the calculation of the gap discount, PDE reporting, and straddle claim processing. We solicited comment on whether there are other topics CMS would need to address in new guidance if we finalized the proposed approach. We also requested that commenters with concerns about the feasibility of sponsors having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit provide detailed explanations of their concerns, with specificity and examples.

In addition, we solicited comment on whether, as an alternative to our proposed approach, we should require that Part D sponsors apply pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap. As noted above, we believe that such a requirement would also be consistent with section 1860D–14A(g)(6) of the Act.

Comment: The majority of commenters indicated that pharmacy price concessions should be included in the negotiated price for applicable drugs in the coverage gap. Commenters stated that applying pharmacy price concessions at the point of sale, regardless of the benefit phase, is the least confusing option for beneficiaries and provides consistency and transparency at the point of sale. Some noted that predictability in out-of-pocket costs is critically important for seniors and people with disabilities. Some commenters believed that applying the same rules regarding the reporting of pharmacy price concessions in the coverage gap would reduce beneficiary out-of-pocket costs and improve patient access and affordability. Several commenters stated that having two different sets of rules would be hard to explain to beneficiaries and create beneficiary confusion. A few commenters raised concerns about how two definitions could be effectively communicated in Medicare Plan Finder files, with greater potential for errors in the information and confusion among enrollees.

Many commenters stated that it would be operationally challenging to have different rules for applying pharmacy price concessions in the coverage gap versus other phases of the Part D benefit. Commenters noted that it was unclear how Part D plans, PBMs, and pharmacies could operationalize two different rules for negotiated prices. Others noted that having two different approaches would increase administrative costs for pharmacies, plan sponsors, PBMs, and other stakeholders, and that claims systems would need to be reprogrammed. Commenters stated that if there were two different approaches, Part D sponsors would need specific guidance regarding the calculation of the gap discount, PDE reporting, and straddle claim processing. In addition, commenters were concerned that having different rules for the negotiated price would result in significant complexity during the bid process and CMS oversight. Some commenters noted the potential for confusion and errors and administrative costs associated with implementation.

Response: We appreciate the thoughtful feedback on maintaining two separate rules for determining the negotiated price and the concerns about the potential for beneficiary confusion, added administrative burden and cost, and implementation challenges that would result from applying one approach to the negotiated price for applicable drugs in the coverage gap phase and another for non-applicable drugs in the gap, as well as for drugs in all other phases of the Part D benefit.

As noted in the preamble of the proposed rule, in the November 2018 proposed rule (83 FR 62179), we solicited comment on whether to require sponsors to include pharmacy price concessions in the negotiated price of applicable drugs in the coverage gap. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has *elected* to pass through at the point-of-sale, we explained that we did not believe it would be appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we indicated our belief that there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular applicable drug. We also noted that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor were required to include all pharmacy price concessions in the negotiated price of an applicable drug, the plan sponsor must still make an election as to how much of the overall price concessions (including non-pharmacy price concessions) it receives will be passed through to beneficiaries at the point-of-sale.

Given our authority under the statute to require plans to include all *pharmacy* price concessions to the negotiated price for all phases of the Part D benefit and the beneficiary confusion, additional administrative burden and costs, and implementation challenges posed by maintaining two approaches for purposes of the two definitions of negotiated price, we are finalizing our proposal with modification to use the negotiated price determined using the lowest possible reimbursement to the pharmacy across all phases of the Part D benefit, including for applicable drugs in the coverage gap phase. Accordingly, we are revising the definition of negotiated price at § 423.2305 to clarify that the negotiated price must be inclusive of all pharmacy price concessions in the coverage gap phase of the Part D benefit but that sponsors continue to have the flexibility to elect which non-pharmacy price concessions are to be passed through at the point of sale. After consideration of the comments, we are finalizing our proposal with modification to use the negotiated price determined using the lowest possible reimbursement to the pharmacy across all phases of the Part D benefit, including the coverage gap phase.

4. Pharmacy Administrative Service Fees

As noted in the proposed rule, we are aware that some sponsors and their intermediaries believe certain fees charged to network pharmacies—such as ''network access fees,'' ''administrative fees,'' ''technical fees,''

and ''service fees''—represent valid administrative costs and, thus, do not believe such fees should be treated as price concessions. However, pharmacies and pharmacy organizations report that they do not receive anything of value for such administrative service fees other than the ability to participate in the Part D plan's pharmacy network.

Thus, we restate the conclusion we provided in the May 2014 final rule (79 FR 29877): When pharmacy administrative service fees take the form of deductions from payments to pharmacies for Part D drugs dispensed to Part D beneficiaries, they clearly represent charges that offset the sponsor's or its intermediary's operating costs under Part D. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis.

The regulations governing the Part D program require that price concessions be fully disclosed. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these amounts did represent costs for services rendered by an intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1) of the regulations) relative to another sponsor that accurately reports administrative costs consistent with CMS instructions.

Comment: Some commenters expressed support for the requirement that legitimate administrative service fees be recorded as administrative costs in the bid and not as a pharmacy price concession. The commenters explained these fees typically provide no additional value to the pharmacy or the beneficiary beyond the ability to participate in the Medicare Part D plan's pharmacy network and instead mainly offset the sponsor's or its intermediary's costs of operating the Part D plan, which the commenters contended should not be the responsibility of a network pharmacy. A few commenters requested that CMS provide further clarification on the definition of pharmacy administrative service fees and what should be considered under such definition.

Response: CMS appreciates the commenters' support. As discussed in the May 2014 final rule (79 FR 29877), pharmacy price concessions characterized as ''network access fees,'' ''administrative fees,'' ''technical fees,'' or ''service fees'' and are taken as deductions from payments to pharmacies for drugs dispensed, represent charges that offset sponsor or PBM operating costs. If a sponsor or its intermediary contracting organization wishes to be compensated for these services then such administrative costs should be accounted for as such in the Part D bid. However, when such fees take the form of deductions from payments to pharmacies for dispensed Part D drugs, such costs are price concessions and must be reflected in the negotiated price. This is the case regardless of whether the deductions are calculated on a per-claim basis. CMS declines at this time to further define what should be considered pharmacy administrative service fees, but we may consider providing further clarification in future rulemaking.

Comment: A commenter requested that CMS clarify how it intends to ensure that administrative service fees are being properly recognized and reported. This commenter recommended that CMS utilize Medicare Part D Reporting Requirements to ensure fees charged to pharmacies are properly reported as either administrative costs or price concessions. Another commenter requested that CMS require a Part D sponsor (and its PBM) attest that any administrative service fees charged by the Part D sponsor (or its PBM) are utilized for administrative services and that such services are relevant and applicable to the pharmacy against which the fees are applied.

Response: We appreciate the concerns raised by commenters and will consider what steps might be necessary in the future to ensure that administrative service fees are properly reported to CMS.

Comment: A number of commenters expressed concerns that the Part D sponsors could use the classifications of price concessions and pharmacy administrative service fees to manipulate the Part D bidding and MLR processes in order to retain additional profit. A commenter was concerned that Part D sponsors had incentives to bid in ways that allowed the sponsors to retain pharmacy price concessions and not apply them to the negotiated price, diminishing the value available to enrollees at the point of sale. This commenter stated that plans overbid by underestimating DIR in order to retain additional profit during the plan's reconciliation process. The commenter is concerned that the terms of the MLR requirements may permit Part D sponsors to inflate their actual expenditures, or ''incurred claims,'' by classifying their arbitrary charges to pharmacies as ''administrative fees'' or ''administrative service fees.'' By doing so, a Part D sponsor inflates their reported incurred claims so that they can retain such fees while simultaneously reducing the sponsor's probability of paying remittances under the MLR. This commenter noted that if such fees were instead reported as post-point-of-sale price concessions, then they would increase the plan's probability of paying a remittance under the MLR. This commenter stated that the MLR requirement was created to encourage plans to: (1) Provide value to beneficiaries, (2) be transparent and accountable for expenditures, and (3) reduce health care costs.

A commenter rejected the notion that Part D plans have an incentive to deliberately underestimate DIR in Part D bids in order to increase plan profits. This commenter stated that there are multiple mechanisms in place to prevent abuse of the system. The commenter cited the bid review process, Part D risk corridors, and the MLR requirement as examples of programmatic features that limit Part D plan sponsors' gaming of bids and profits. The commenter asserts that the Office of the Actuary would refuse to approve bids if a sponsor were ''consistently off'' in projections. They contended that the current plan payment structure applies appropriate incentives and allows for appropriate oversight to ensure that private market innovation delivers competitive and meaningful choices to beneficiaries and financial savings to taxpayers.

Response: While the bid review process, Part D risk corridors and the MLR requirement limit Part D plan sponsors' ability to game bids and profits to an extent, we do not agree with the commenters' implication that these are CMS. The commenters do not address the analysis of Part D plan payment and cost data we discussed in the proposed rule, which show that in recent years, DIR amounts that Part D

sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by an average of 0.6 percent and as much as 3 percent as a share of gross drug costs from 2010 to 2020. The commenter merely asserts that the Office of the Actuary would have refused to approve bids if a sponsor were ''consistently off'' in projections. They fail to elaborate under which conditions the Office of the Actuary would reject a bid from a Part D sponsor because the Part D sponsor has been historically off in their bids, but could provide an argument that their current bid is actuarially sound. We do not believe the MLR requirement nor the Part D risk corridors function to solve or disincentivize the trend of underbidding DIR. The MLR requirement mandates that sponsors remit funds if less than 85 percent of all revenues are spent on prescription drugs or quality improvement activities. When Part D sponsors share extra profits through the Part D risk corridor with the Federal Government due to the sponsor underestimating DIR, sponsors typically keep a significant majority of the extra profits. For example, when a Part D sponsor's target amount or revenue exceeds their allowable risk corridor costs by 10%, the sponsor would retain 75% of the extra profits while the Federal Government would recoup 25%. Also, a Part D sponsor could underestimate DIR relative to its bid and receive additional profits up to the maximum amount permitted by the Part D risk corridors without necessarily failing to meet the 85 percent MLR requirement.

CMS appreciates the commenter's concerns that Part D sponsors could manipulate the treatment of payments from pharmacies in different Part D processes in order retain additional profits. However, we believe the requirements for both MLR and under this final rule are clear that a Part D sponsor could not treat a fee as an administrative cost for one purpose, but a drug cost for the other. While Part D sponsors have had an incentive to bid using an assumption that pharmacy price concessions would not be applied at the point of sale to achieve advantageous premiums, Part D sponsors must submit Part D bids that comply with the Part D statute, regulations, and rules applicable for the contract year as the basis for their actuarial assumptions, and in relation to the issuance of this final rule Part D sponsors will be required to reflect the new definition of negotiated price in all phases of the Part D benefit in their Part D bids. The definition of ''price concession'' and the requirements of the MLR would not allow Part D sponsors to inflate the ''incurred claims'' in their MLR by reclassifying amounts that are deducted from payments made to pharmacies for purchases of Part D drugs as administrative fees. ''Incurred claims'' in the MLR numerator include direct drug costs that are actually paid (§ 423.2420(b)(2)(i)) and excludes administrative fees (§ 423.2420(b)(4)). The definition of ''price concession'' mirrors ''actually paid'' as defined in § 423.308. A ''price concession'' is defined as any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Similarly, ''actually paid'' are costs that must be actually incurred by the Part D sponsor and must be net of DIR from a source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Therefore, any amount that would be considered a price concession in the application of this rule would also be netted from the incurred claims amount in the MLR numerator, which is why we believe the requirements for both MLR and this final rule are clear that a Part D sponsor could not treat a fee as an administrative cost for one purpose, but a drug cost for the other.

5. Defining Price Concession (§ 423.100)

Section 1860D–2(d)(1)(B) of the Act stipulates that the negotiated price shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs. Section 1860D–2(d)(2) of the Act further requires that Part D sponsors disclose to CMS the aggregate negotiated price concessions by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. While ''price concession'' is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute or in Part D regulations and sub-regulatory guidance. Therefore, to avoid confusion among Part D sponsors and other stakeholders of the Part D program resulting from inconsistent terminology, we proposed to add a regulatory definition for the term ''price concession'' at § 423.100 that is consistent with how that term is used in subsections (d)(1)(B) and (d)(2) of section 1860D–2 of the Act.

We proposed to define price concession to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. The proposed definition would note that price concessions include but are not limited to discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

The proposed rule noted that adopting the proposed definition of price concession would not affect the way in which price concessions must be accounted for by Part D sponsors in calculating costs under a Part D plan, and it would not require the renegotiation of any contractual arrangements between a sponsor and its contracted entities. Therefore, the proposed definition of price concession has no impact under the Federal requirements for Regulatory Impact Analyses.

Comment: Many commenters expressed concern that PBMs will restructure pharmacy fees to sources other than claim-level fees to circumvent CMS's intent in the proposal and provided recommendations on what CMS should include or consider. Some commenters wanted CMS to clarify that pharmacies would not be held accountable for ''non-pharmacy'' price concessions (for example, manufacturer rebates).

Many commenters asked CMS to confirm that any fee related to or assessed because of a Part D prescription drug claim is considered a price concession. Commenters expressed that this should be true whether the fee represents an administrative fee, a transaction fee, or the value of a contingent amount, such as a performance-based penalty. Many commenters explained that the fees and price concessions that PBMs utilize in contracts and pharmacy manuals have different names, but were primarily deductions from their reimbursements. Commenters felt these deductions must be treated as a price concession and fully disclosed to them on individual adjudicated claim responses and remittance advices within the prompt pay rules of 14 calendar days.

Response: We believe that the definition of ''price concession'' that we discussed in the proposed rule is broad enough to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors, so that Part D sponsors and their intermediaries are limited in

circumventing CMS' intent without fundamentally changing. When pharmacy administrative service fees take the form of deductions from payments to pharmacies, they represent charges that offset the sponsor's or its intermediary's operating costs under Part D. If the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should have been accounted for in the administrative costs of the Part D bid. However, if the sponsor or its intermediary deducts these same costs from payments to pharmacies, such costs are price concessions and must be reflected in the negotiated price. For pharmacy price concessions that are not at the claim level, Part D sponsors would have to determine a methodology to attribute such concessions to the claim level to remain in compliance with the definition of negotiated price.

We are confirming that under the definition of negotiated price we are adopting in this final rule, the negotiated price must include pharmacy price concessions, and does not require inclusion of non-pharmacy price concessions, such as manufacturer rebates. To the extent a non-pharmacy price concession is applied to the negotiated price, it would reduce the negotiated price, but not reduce the amount that is the lowest possible reimbursement the pharmacy could receive as reimbursement for a covered Part D drug under the contract between the pharmacy and the Part D sponsor or the sponsor's intermediary.

Comment: Some commenters recommended changes to our proposed definition of ''price concession.'' These commenters recommended that the definition consider administrative service fees. A commenter recommended that in our proposed definition after the phrase ''received by the Part D sponsor or its intermediary contracting organization'' that we add ''for a particular claim at any time during the contract year.'' This commenter also recommended that after the phrase ''from any source'' that we add ''including a network dispensing pharmacy.'' Finally, in the list of examples of price concessions, the commenter recommended that we include ''fees or other charges to network dispensing pharmacy.'' Another commenter recommended that we modify the definition of ''price concession'' by adding, after the phrase ''that serves to decrease the costs incurred under the Part D plan by the Part D sponsor,'' ''or its intermediary contracting organization under the Part D plan.'' This commenter also recommends that the examples be expanded to include ''any type of fee or other amount that a Part D sponsor or its intermediary contracting organization retains from payments made to such pharmacies or providers for their provision of Part D drugs or requires such pharmacies or providers to pay in connection with its provision of Part D drugs under a Part D network, including but not limited to transaction fees, network participation fees and administrative fees.'' Commenters also requested that CMS define ''administrative service fees.''

Response: For the reasons stated previously, we believe the definition we are adopting in this final rule is sufficient to identify price concessions. CMS will take commenters' suggestions for changes to the definition of price concession, as well as for a new definition of ''administrative service fees,'' into consideration for future rulemaking.

We are finalizing our proposal without modification to define ''Price concession'' to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor at § 423.100.

III. Requests for Information

A. Request for Information: Prior Authorization for Hospital Transfers to Post-Acute Care Settings During a Public Health Emergency

We are committed to ensuring that hospitals, post-acute care facilities (including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), and skilled nursing facilities (SNFs)), physicians, and MA organizations have the tools necessary to provide access to appropriate care to patients without unnecessary delay during a public health emergency (PHE). Throughout 2020 during the Coronavirus Disease 2019 Public Health Emergency (COVID–19 PHE), we consistently issued guidance to address permissible flexibilities for MA organizations as part of an ongoing effort to help MA enrollees, and the health care systems that serve them, avoid delays and disruptions in care. We recognize that any delays or disruptions in care that might transpire within the MA program could have a ripple effect and also negatively impact the timely provision of appropriate care to patients covered under payer systems external to MA (for example, employer-sponsored insurance). Additionally, we recognize the positive impact that payers in general can have through the adoption of flexibilities that support hospitals' ability to effectively manage resources when a hospital experiences a substantial uptick in hospitalizations.

As a result of the guidance and clarification that we issued throughout 2020, a large proportion of MA organizations opted to relax or completely waive their prior authorization requirements with respect to patient transfers between hospitals and post-acute care facilities during plan year 2020, consistent with our guidance encouraging flexibility to ensure access to care. However, as the PHE continued into 2021, many MA organizations reinstated prior authorization requirements, which some stakeholders reported contributed to capacity issues and delays in care within hospital acute care settings. For example, one stakeholder reported that only 5 percent of intensive care unit (ICU) beds were open in their state during the month of August 2021, and stated that the scarcity of available beds could be mitigated if more MA organizations reinstated waivers on prior authorization requirements for patient transfers. Another stakeholder reported that it was not uncommon for a hospital to wait up to 3 business days to receive a decision from an MA organization for a request for a patient transfer—a delay which prevented the hospital from moving patients to the next appropriate care setting in a timely manner and forced the unnecessary use of acute-care beds. The same stakeholder reported that a high rate of initial denials from MA organizations also contributed to delays in patient transfer. We acknowledge our responsibility to ensure that our programs' policies do not hinder access to care, especially during a public health emergency. Therefore, in response to these reports and the uptick in COVID–19 hospitalizations across the country, we sought information from stakeholders in order to assess the impact of MA organizations' use of prior authorization or other utilization management criteria during certain PHEs. Through this request for information (RFI), CMS sought additional information from all affected stakeholders, especially MA organizations, hospitals, post-acute care facilities, professional associations, states, and patient advocacy groups regarding the effects of both the relaxation of and reinstatement of prior authorizations on patient transfers during a PHE.

We noted that we remain mindful of the impact the MA program's policies have on the health care system as a whole, and strongly encouraged MA organizations to continuously re-assess the need for flexibilities in their utilization management practices. We noted that with regard to prior authorization and other utilization management practices, we permit MA organizations the choice to uniformly waive or relax plan prior authorization requirements at any time in order to facilitate access to care, even in the absence of a disaster, declaration of a state of emergency, or PHE. Generally, MA organizations are required to ensure that enrollees are notified of changes in plan rules of this type in accordance with § 422.111(d); however, when the provisions under § 422.100(m)(1) go into effect during a disaster or emergency, as they did during the COVID–19 PHE, MA organizations are permitted to immediately implement plan changes that benefit enrollees, including a waiver of prior authorization requirements, without the 30-day notification requirement at § 422.111(d)(3).

We invited the public to submit comments for consideration as CMS assesses the impact of MA organizations' prior authorization requirements for patient transfer on a hospital's ability to effectively manage resources and provide appropriate and timely care during a PHE. We indicated that the primary objective of this RFI was for us to glean information from stakeholders about the effects of MA organizations' prior authorization requirements for patient transfers on a hospital's ability to furnish the appropriate care to patients in a timely manner in the context of a PHE. This was a general RFI related to prior authorizations on patient transfers during any PHE. While many commenters may have chosen to provide information in the context of the COVID–19 PHE, we welcomed and encouraged commenters to provide information in the context of any PHE.

B. Request for Information: Building Behavioral Health Specialties Within MA Networks

CMS is dedicated to ensuring that MA beneficiaries have access to provider networks sufficient to provide covered services in accordance with the standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1). Accordingly, CMS strengthened network adequacy rules for MA plans by codifying our network adequacy standards at § 422.116 in the June 2020 final rule.

Currently, we require MA organizations to submit data for behavioral health providers, specifically psychiatry (provider-specialty type) and inpatient psychiatric facility services (facility-specialty type), using the Health Service Delivery (HSD) tables. The HSD tables are submitted to CMS during an MA organization's formal network review and are utilized to demonstrate compliance with network adequacy standards. The HSD tables must list every provider and facility with a fully executed contract in the MA organization's network, and are uploaded to the Health Plan Management System (HPMS) for an automated review. MA plans must have sufficient providers within a certain time and distance of 85 or 90 percent of beneficiaries residing the plan's service area, depending on the type of counties in the service area, under § 422.116. We also encouraged plans to provide more choices for enrollees to access care using telehealth for certain specialties, including psychiatry, through our policy under § 422.116(d)(5), while maintaining enrollees' right to access in person care for these specialty types. To encourage and account for telehealth providers in contracted networks, § 422.116(d)(5) provides MA plans a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan's network includes telehealth providers for certain specialties and the plan covers additional telehealth benefits, as defined in § 422.135. However, as noted in the proposed rule, even with the availability of the additional 10-percentage point credit for the use of telehealth providers, it is our understanding that MA organizations may experience difficulties meeting network adequacy standards with respect to behavioral health providers.

In order to increase our understanding of issues related to MA enrollees' access to behavioral health specialties, CMS sought input from industry stakeholders on the challenges MA organizations face when building an adequate network of behavioral health providers for MA plans. More specifically, we issued an RFI that solicited comment on issues including, but not limited to, the following:

- Challenges related to a lack of behavioral health provider supply in certain geographic regions for beneficiaries, health plans, and other stakeholders;
- Challenges related to accessing behavioral health providers for enrollees in MA plans, including wait times for appointments;
- The extent to which a behavioral health network affects a beneficiary's decision to enroll in an MA plan;
- Challenges for behavioral health providers to establish contracts with MA plans;
- Providers' inability or unwillingness to contract with MA plans, including issues related to provider reimbursement;
- Opportunities to expand services for the treatment of opioid addiction and substance use disorders;
- The overall impact of potential CMS policy changes as it relates to network adequacy and behavioral health in MA plans, including in rural areas that may have provider shortages; and
- Suggestions from industry stakeholders on how to address issues with building adequate behavioral health networks within MA plans.

We acknowledge and appreciate all comments submitted in response to this RFI. While we will not be responding to those comments in this final rule, we will take the commenters' suggestions, concerns, and other feedback into account as we consider future changes to our in policy in this area.

C. Request for Comment on Data Notification Requirements for Coordination-Only D–SNPs (§ 422.107(d))

In the April 2019 final rule, we established an additional contracting requirement at § 422.107(d) for any D–SNP that is not a FIDE SNP or HIDE SNP. Under this new requirement for the contract that is required between the D–SNP and the State Medicaid agency effective January 1, 2021, the D–SNP is required to notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the State Medicaid agency.

These data notification requirements have only been in effect for a short time, all of which coincided with the COVID–19 public health emergency. Through the proposed rule we invited MA organizations, States, and other stakeholders to submit comments on their experience implementing the data notification requirements thus far and any suggested improvements for CMS consideration in future rulemaking.

While we are not responding to specific comments submitted in response to this Hospital Transfers to Post-Acute Care Settings during a Public Health Emergency, Building Behavioral

Health Specialties within MA Networks, Data Notification Requirements for Coordination-Only D–SNPs request for information (RFI) in this final rule, we appreciate all of the comments and interest on these topics. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on these topics and may reach out to commenters for further discussion.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) 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. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our January 12, 2022 (87 FR 1842) proposed rule, we solicited public comment on each of these issues for the following provisions that contain information collection requirements. As indicated below, we received public comments on the collection of information requirements related to the creation of a one-page multi-language insert; the comments and our responses are summarized below under the applicable Collection of Information subsection. Separately, on February 25, 2022 (87 FR 10761), we published a correction that clarified we will submit information on the number of respondents and the time estimates to the public and OMB for the collection of information requirements related to limiting certain Medicare Advantage contracts to D–SNPs prior to the 2025 plan year application.

A. Wage Data

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*), which, at the time of finalizing of this rule, provides May 2021 wages. In this regard, Table 3 presents BLS's mean hourly wage along with our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 3: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operation Specialists, All Other	13-1199	38.10	38.10	76.20
Compliance Officers	13-1041	36.45	36.45	72.90
Computer and Information Systems Managers	11-3021	78.33	78.33	156.66
Lawyer	23-1011	71.17	71.17	142.34
Software Developers	15-1252	58.17	58.17	116.34

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent to account for fringe benefits and overhead costs that vary from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2020 wages, this final rule uses BLS's May 2021 wages which are the most current as of the publication date of this rule. The wage changes are presented below in Table 4. Overall, the revised BLS wages increased our cost estimates by $74,274 for first year (from $5,225,170 to $5,299,444) and a corresponding decrease of $43,579 for subsequent years (from $3,647,583 to $3,604,004). Note these numbers also reflect an adjustment to the numbers published in the January 2022 proposed rule (87 FR 1934) since two provisions described in section IV.B.2 and section IV.B.3. had changes in their estimated number of respondents, and in response to comments one additional provision (section IV.B.7.) was added. Therefore, we recalculated the estimates from the proposed rule with these three changes resulting in $5,225,170 for first year and $3,647,583 for subsequent years representing the updated estimates with 2020 wage estimates. We then recalculated again using the 2021 wage estimates resulting in the $5,299,444 for first year and the $3,604,004 for subsequent years numbers so that the difference would compare similar items.

Please note that besides the wage changes there were (i) two changes in occupation codes, 13–1198 is now 13–1199 and 15–1250 is now 15–1252 and (ii) there was one change in occupational title, ''Software and Web Developers'' is now ''Software developers.''

TABLE 4: COMPARISON OF PROPOSED AND FINALIZED ADJUSTED HOURLY WAGES

Occupation Title	Occupation Code	CMS-4192-P: BLS May 2020 ($/hr)	CMS-4192-F: BLS May 2021 ($/hr)	Difference ($/hr)
Business Operation Specialists, All Other	13-1198	81.06	76.20	-4.86
Compliance Officers	13-1041	72.70	72.90	0.20
Computer and Information Systems Managers	11-3021	155.52	156.66	1.14
Lawyer	23-1011	143.18	142.34	-0.84
Software and Web Developers	15-1250	105.72	116.34	10.62

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within section II. of this final rule.

1. ICRs Regarding Enrollee Participation in Plan Governance (§ 422.107) (CMS–10799, 0938–1422)

The requirement and burden for D–SNPs to create one or more enrollee advisory committees will be submitted to OMB for approval under control number 0938–TBD (CMS–10799). The requirement and burden for D–SNPs to update audit protocols to require documentation of the enrollee advisory committees will be submitted to OMB for approval under control number 0938–1395 (CMS–10717).

a. Creating One or More Enrollee Advisory Committees (CMS–10799, OMB 0938–1422)

At § 422.107(f), we are requiring that any MA organization offering a D–SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We also require at § 422.107(f) that the committee include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan, or plans, or other individuals representing those enrollees, and solicit input from these individuals or their representatives on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

The burden of establishing and maintaining an enrollee advisory committee is variable due to the flexibilities MA organizations would have to implement the requirements. We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement; therefore, we chose not to establish the: (1) Frequency; (2) location; (3) format; (4) participant recruiting and training methods; (5) use and adoption of telecommunications technology; or (6) other parameters for operation of the required committee. In addition, the final rule requires one committee (for example, one committee at the State level to serve all of the MA organization's D–SNPs in that State) but MA organizations may establish more than one committee). This rule also permits MA organizations to use existing committees which would meet the requirements of both §§ 422.107(f) and 438.110 (we expect this approach to be used by FIDE and HIDE SNPs).

The only requirements in this rule for an MA organization offering one or more D–SNPs in a State is to establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization and for that committee to solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. The enrollee advisory committee(s) must include at least a reasonably representative sample of the population enrolled in the D–SNP(s), or other individuals representing those enrollees. The enrollee advisory committee(s) may also advise managed care plans under title XIX of the Act offered by the same parent organization as the MA organization offering a D–SNP.

To determine the burden for MA organizations to establish the enrollee advisory committees, we reviewed two estimates from similar committees. First, the May 2016 final rule (81 FR 27778) estimated it will take 6 hours annually for a business operations specialist to establish and maintain the LTSS member advisory committee required by § 438.110 for Medicaid managed care plans that cover Medicaid LTSS.

Second, in 2021 we conducted an informal survey of the three South Carolina MMPs under the capitated FAI demonstration that are required to conduct meetings quarterly and highly value their advisory committees. The MMPs surveyed estimated an annual average of 240 hours (or 60 hours per meeting) to recruit members and establish and maintain the committee. We expect these efforts to include outreach and communication to members, developing meeting agendas, scheduling participation of presenters, preparing meeting materials, identifying meeting location and technology, D–SNP staff attendance at the meeting, and disseminating enrollee feedback to D–SNP and MA organization staff.

Due to the variety of flexibilities in creating the enrollee advisory committee, detailed previously in this section, we expect the average time and annual cost for an MA organization to establish and hold an enrollee advisory committee meeting(s) to be somewhere between 6 hours estimated for the requirement at § 438.110 and 240 hours as reported by MMPs. We believe this large difference in the time spent comes from two sources: (1) The committees created by MMPs must meet quarterly rather than annually and (2) MMPs find value in their committees and have invested more staff and resources to recruit enrollees, and prepare for and hold meetings; for example, MMPs often provide transportation to meetings, refreshments, and nominal incentives for participation, none of which is required by the capitated FAI demonstration or this rule. With this understanding that a wide variety of approaches would be used, we estimate that on average a business compliance officer will spend 40 hours at $76.20/hr to establish and hold enrollee advisory committee meetings.

In the proposed rule, we noted that each MA organization offering one or more D–SNPs in a State will decide how to establish an enrollee advisory

committee based on the MA organization's approach to obtaining maximal input from enrollees leading to the highest quality enrollee experience. Because of the wide variability, we solicited stakeholder comments on our assumptions and burden estimates. We received no comments on this issue and therefore we are finalizing our estimates that an MA organization will spend 40 hours at a cost of $3,048 (40 hr × $76.20/hr for a business operation specialist) to establish an enrollee advisory committee.

We believe all FIDE SNPs and HIDE SNPs that provide LTSS currently have an enrollee advisory committee since they have a Medicaid managed care plan that must comply with § 438.110. We are updating these estimates from the estimates used in the proposed rule based on the increase in D–SNP PBPs for contract year 2022. There were 596 D–SNP PBPs in 2021 and 703 D–SNP PBPs in 2022. For 2022, we estimate 578 D–SNPs do not have a corresponding Medicaid managed care plan that provides LTSS, with 125 D–SNP PBPs in MA contracts that provide LTSS. Additionally, 268 D–SNP PBPs are in the same State and under the same contract, which means only one enrollee advisory committee is necessary to meet the requirement. Therefore, we estimate MA organizations operating D–SNPs will need to establish 310 (703 D–SNP PBPs minus 125 PBPs in D–SNP contracts that provide LTSS minus 268 PBPs under the same contract in the same State) new enrollee advisory committees.

Thus, the aggregate minimum annual burden for MA organizations operating D–SNPs to meet the requirements of § 422.107(f) is 12,400 hours (310 new committees × 40 hr per committee) at a cost of $944,880 (12,400 hr × $76.20/hr). As stated above, the requirement and burden will be submitted to OMB for approval under control number 0938–1422 (CMS–10799).

b. Updates to Audit Protocols (CMS–10717, OMB 0938–1395)

As noted in section II.A.3. of this rule, we anticipate updating the CMS SNP Care Coordination audit protocols [94] for MA organizations offering one or more D–SNPs to require documentation, such as a committee member list and meeting minutes, of the enrollee advisory committee meetings. In our currently approved collection of information request, we estimated that the audit protocol and data request will take 701 hours per MA organization at an average hourly cost of $87.00/hr, totaling $60,987 per MA organization (701 hr × $87.00/hr). With regard to this final rule, we believe MA organizations offering D–SNPs will prepare and retain a committee member list and meeting minutes a of customary business practices that is exempt from the requirements of the PRA under 5 CFR 1320.3(b)(2). Therefore, we do not believe reporting this documentation on the enrollee advisory committee will impact our currently approved 701-hour audit protocol time estimate.

While we do not anticipate any changes to our active time estimates, we will revise the SNP Care Coordination audit protocol prior to the effective date of the rule to provide stakeholders with an opportunity to comment on the contents of our revised audit protocol. The CMS–10717 collection of information request will be made available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

c. Conclusion

We did not receive any public comments on our proposed collection of information requirements, however, as noted and explained previously in this section, we have updated to our estimates based on: (1) The increase of D–SNP PBPs for contract year 2022; and (2) updated hourly wage estimates.

2. ICRs Regarding Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101) (CMS–10799, OMB 0938–1422) and (CMS–10717, OMB 0938–1395)

The following HRA requirements will be submitted to OMB for approval prior to the CY 2024 applicability date. The changes to our SNP audit protocols will be submitted to OMB for approval under control number 0938–1395 (CMS–10717).

a. Added HRA Questions

As described in section II.A.4. of this final rule, we are requiring that SNPs include questions on housing stability, food security, and access to transportation as part of their HRAs, although, based on insight from public comments, we are not finalizing our proposal to require standardized questions as proposed in our January 2022 proposed rule. Instead, we will require SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. SNPs will also have the option to use any State-required Medicaid screening instruments that include questions on these domains. We have updated our burden estimates accordingly, as described later in this section. As noted in section II.A.4. of this final rule, we will ensure compliance with the PRA as we strive to post the sub-regulatory guidance by the end of 2022.

This provision will result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We do not believe that collecting this information will require any additional efforts from SNPs outside of customary updates to the HRA tools. Due to the current requirement at § 422.101(f) that the HRA include an assessment of the individual's physical, psychosocial, and functional needs, we believe, and public comments confirmed, that many SNPs are already including questions in their HRA tools related to housing stability, food security, and access to transportation, and many such questions are drawn from the types of validated and widely-used screening instruments that we will specify in sub-regulatory guidance. Therefore, many SNPs will not need to revise their HRA tools. If a SNP is not already asking these questions, we do not predict the addition of questions on these three topics would lengthen the time to administer a typical HRA.

CMS does not currently collect specific data elements from HRAs for all SNP enrollees. CMS will not be collecting data elements from the HRA as part of this collection of information.

We estimate a one-time burden for the parent organizations offering SNPs to update their HRA tools in their care management systems and adopt questions on housing stability, food security, and access to transportation, in cases where the SNPs are not already asking questions on the required topics.

In our proposed estimate, we assumed that each parent organization offering one or more SNP would be impacted. Because we are not finalizing standardized questions but rather requiring SNPs to choose questions from a list of existing screening instruments that comments indicate are widely in use or a State-required Medicaid screening instruments, we assume that many SNPs are already asking questions that we will include on the list; therefore, we estimate about 35 percent of parent organizations with one or

[94] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

more SNPs would update the care management system where an enrollee's HRA responses are recorded. We estimate that it will take a software programmer 3 hours at $116.34/hr to update the care management system resulting in a cost of $349 (3 hr × $116.34/hr) per parent organization. We are updating the number of parent organizations making these updates based on the 2022 contract year numbers from 123 parent organizations with a SNP PBP in 2021 to 133 parent organizations with a SNP PBP in 2022. We therefore estimate 47 parent organizations (35 percent of organizations that update multiplied by 133 parent organizations) will be making these updates. In aggregate, we estimate a one-time burden for updating the HRA tool of 141 hr (47 parent organizations × 3 hr) at a cost of $16,404 (141 hr × $116.34/hr).

b. Updates to Audit Protocols (CMS–10717, OMB 0938–1395)

The change to the HRAs would also require an update to the CMS SNP Care Coordination audit protocols [95] that ensure the completed HRAs include the assessment of housing stability, food security, and access to transportation based on the list of screening instruments specified by CMS in sub-regulatory guidance. Currently, audit protocol and data request burden are estimated at 701 hours per MA organization at an average hourly cost of $87.00/hr, totaling $60,987 per MA organization. We do not believe the changes to SNP audit protocols would add more time to the 701-hour audit protocol estimate, as we are adding a confirmation that the SNP's HRA includes the changes as part of the SNP Care Coordination audit protocols.

While we do not anticipate any changes to our active time estimates, we will revise the audit protocol documents to provide stakeholders an opportunity to review and comment on the contents of the protocol documents. The revised collection of information request is not available at this time, but it will be made available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

c. Conclusion

We did not receive any public comments on our proposed collection of information requirements regarding housing, food insecurity, and transportation questions on health risk assessment. As indicated above, (i) we have updated our burden estimates from 123 affected parent organizations to 47 parent organizations and (ii) updated our cost estimates by using BLS' 2021 wages; however, the estimated time per respondent remains the same.

3. ICRs Related To Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§ 422.2)

The following changes will be submitted to OMB for approval under control number 0938–1410 (CMS–10796).

As described in section II.A.5. of this final rule, we are making several changes to the definitions of FIDE SNPs and HIDE SNPs at § 422.2 that we believe will ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries and stakeholders. Our changes to the FIDE SNP definition require these plans to: Have exclusively aligned enrollment; cover Medicare cost-sharing; and cover the Medicaid benefits of home health (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and Medicaid behavioral health services through a capitated contract with the State Medicaid agency. We also require that each FIDE SNP's and HIDE SNP's capitated contract with the State Medicaid agency apply to the entire service area for the D–SNP for plan year 2025 and subsequent years. We are also codifying existing policy outlined in sub-regulatory guidance to permit, subject to CMS approval, specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs through the State Medicaid agency contract submission process.

Due to the changes to the definition of FIDE SNP and HIDE SNP, a D–SNP may need to update its contract with the State Medicaid agency. The currently approved annual burden estimate for updating the State Medicaid agency contract is 30 hours per D–SNP as described in OMB control number 0938–0753 (CMS–R–267). While the changes may result in a one-time change to the contract, we believe the changes to the contract language would be relatively minor (even though the changes are substantive in nature) and part of routine updates to contracts such as changes of dates. We also believe that the contract changes would be subsumed in the 30-hour burden estimate for updating the contract annually. Therefore, we do not estimate our changes to these definitions at § 422.2 would impact our currently approved annual 30 hour contracting burden estimate for D–SNPs.

The changes to the FIDE SNP and HIDE SNP definitions may change how D–SNPs attest when submitting their State Medicaid agency contract to CMS. The burden is currently estimated under OMB control number 0938–0935 (CMS–10237). We do not estimate D–SNPs would experience an increase in their per response time or effort to submit the State Medicaid agency contract to CMS.

However, we will update the content of the collection of information to reflect the changes to § 422.2 by revising the 5.11 D–SNP State Medicaid Agency Contract Matrix and 5.12 D–SNP State Medicaid Agency Contract Matrix documents connected to control number 0938–0935 (CMS–10237) and move these documents to control number 0938–1410 (CMS–10796). We believe including these forms in a separate OMB control number 0938–1410 (CMS–10796) exclusively for the D–SNP State Medicaid agency contracts is more operationally consistent with the collection of information required from MA organizations. The matrix documents will be removed from 0938–0935 after they are approved by OMB under 0938–1410.

a. Service Area Overlap Between HIDE SNPs and Companion Medicaid Plans (CMS–R–262, OMB 0938–0763)

In addition to the updates described in this section, changes to the FIDE SNP or HIDE SNP definition described in section II.A.5.f. of this final rule will require the service area of a FIDE SNP or HIDE SNP to overlap with companion Medicaid plans; therefore, the 15 HIDE SNPs that have service area gaps with their affiliated Medicaid MCOs would make a business decision regarding how to comply with the requirement in addition to updating the State Medicaid agency contract with the D–SNP. We believe that only one-third of the 15 impacted D–SNPs, or 5 D–SNPs, would choose to remain a HIDE SNP. The remaining 10 D–SNPs would contract with the State as a non-HIDE D–SNP and not incur additional burden.

A D–SNP that wishes to remain a HIDE SNP would submit a new D–SNP PBP for the service area that does not overlap with the D–SNP's companion Medicaid plan during the annual bid submission process (OMB control number 0938–0763 (CMS–R–262)). Also, under the annual bid submission process, the existing HIDE SNP would reduce their MA service area to that which overlaps with the companion Medicaid plan.

[95] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

The currently approved annual burden estimate for D–SNPs to update PBPs is 35.75 hours per MA contract as described in OMB control number 0938–0763 (CMS–R–262). We do not estimate D–SNPs would experience an increase in their response time or effort to submit the bid to CMS.

Alternatively, to remain a HIDE SNP, the MA organization can work with the State Medicaid agency to expand the service area of the companion Medicaid plan to align with the D–SNP service area. However, State Medicaid procurement time frames and contracting strategies may not provide the 15 D–SNPs an opportunity to expand the service area of the companion Medicaid plan in CY 2025.

b. Conclusion

We did not receive any public comments on our proposed collection of information requirements and are therefore finalizing them without modification.

4. ICRs Related to Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this final rule, we are adding new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D–SNPs and how CMS would facilitate compliance with those contract terms. Paragraph (e)(1) would allow States, through the State Medicaid agency contract with D–SNPs, to require that certain D–SNPs with exclusively aligned enrollment (a) establish MA contracts that only include one or more D–SNPs within a State, and (b) integrate materials and notices for enrollees. A more detailed discussion of these requirements and associated burden follows:

a. State Medicaid Agency Contract Requirements

The following changes will be submitted to OMB for review under control number 0938–1410 (CMS–10796).

For States that opt to require the contract requirements at § 422.107(e), States and plans will need to modify the existing State Medicaid agency contract. These modifications will document the D–SNP's responsibility to only enroll dually eligible individuals who receive coverage of Medicaid benefits from the D–SNP, integrate member materials, and request that CMS establish an MA contract limited to D–SNPs within the State.

(1) State Burden (CMS–10796, OMB 0938–1410)

Section 1903(a)(7) of the Act requires the Federal Government to pay a match rate for administrative expenses. Since cost is split between the State Medicaid agency and the Federal Government, we split in half the total costs associated with administering the Medicaid program, half of which the States incur and half of which the Federal Government incurs. The Federal Government's cost is presented in the RIA section of this rule (see section V.D.3.).

For each State Medicaid agency, it will take a total of 24 hours at $142.34/hr for State staff to update the State Medicaid agency's contract with the D–SNPs in its market to address the changes in this final rule. This estimate includes the burden to negotiate with the D–SNPs on contract changes and engage with CMS to ensure contract changes meet the requirements that we are finalizing at § 422.107(e).

Based on our experience, we expect that each State Medicaid agency will establish uniform contracting requirements for all D–SNPs operating in their market. We are uncertain of the exact number of States that would opt to require these proposed contract changes over the course of the first 3 years (contract years 2025 to 2027). Based on our previous work with States as part of the capitated FAI demonstration and implementing the D–SNP integrations requirements established by the BBA of 2018, we estimate as few as five and as many as 20 States may opt to make these changes in their contracts with D–SNPs and their administration of their programs. Based on the number of States currently collaborating with CMS on Medicare and Medicaid integration and the States likely to transition from MMP-based to D–SNP-based integrated care approaches, we believe there will be 12 States that implement this rule. In our proposal, we projected that States would implement this one-time change during the first year (contract year 2025). In section II.A.14. of this final rule, we discuss our intent to explore extension of the FAI model test in certain circumstances and consistent with our authority under section 1115A of the Act to convert MMPs to integrated D–SNPs. The discussion in section II.A.14. of this final rule makes us less certain of when States will incur the burden described in this collection of information; however, we do not expect the number of States impacted to change. Therefore, we are not updating our estimates based on the discussion in section II.A.14. of this final rule.

Section 1903(a)(7) of the Act requires the Federal Government to pay half of the States' administrative costs. In aggregate we estimate a one-time burden of 288 hours (12 States × 24 hr/State) at a cost of $20,497 (288 hr × $142.34/hr × 0.5). After this first-year one-time requirement is satisfied, and given the uncertainty involved in estimating State behavior, we are estimating zero burden in subsequent years.

(2) MA Organization Burden (CMS–10796, OMB 0938–1410)

For the initial year, we expect each affected D–SNP will take 8 hours at $142.34/hr for a lawyer to update the contract with the State Medicaid agency to reflect the revised and new provisions in this rule at § 422.107(e). Based on our assumptions of States likely to opt to require the contract changes, we estimate between 40 to 80 MA organizations would be impacted. Since we are uncertain of which extreme to use, we use the average, 60 MA organizations. We further expect the updates to be completed in the first year (contract year 2025). In aggregate we estimate a one-time burden of 480 hours (60 MA organizations × 8 hr) at a cost of $68,323 (480 hr × $142.34/hr).

b. Limiting Certain Medicare Advantage Contracts to D–SNPs (CMS–10237, OMB 0938–0935 and CMS–10137, OMB 0938–0936)

The following changes regarding additional Part C application respondents will be submitted to OMB for approval under control number 0938–0935 (CMS–10237). The following changes regarding additional Part D application respondents will be submitted for OMB approval under control number 0938–0936 (CMS–10137).

At § 422.107(e) we are codifying a pathway by which States can require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more D–SNPs with exclusively aligned enrollment within a State. This action will allow dually eligible individuals to ascertain the full quality performance of a D–SNP and better equip States to work with their D–SNPs to improve health equity.

We note that creating a new D–SNP-only contract will have several downstream collection of information impacts for an MA organization that are captured under the two aforementioned control numbers, the most immediate of which is the MA organization would

need to complete a new application for Parts C and D.

We estimate that 60 D–SNPs will be impacted by our changes to § 422.107(e). Currently, 32 percent of D–SNPs are in D–SNP-only contracts; [96] therefore, we estimate that 19 of the 60 D–SNPs (60 D–SNPs × 0.32) impacted would already have a D–SNP-only contract and not need to submit a new Part C and D application. The remaining 41 D–SNPs (60 − 19 D–SNPs) would need to submit both a new Part C and a new Part D application.

The burden per MA organization for an initial Part C application for a SNP is currently approved by OMB under control number 0938–0935 (CMS–10237) at 10 hours at $72.90/hr for a compliance officer to review instructions and complete the application (including submission) at a cost of $729 (10 hr × $72.90/hr). Under this final rule, we estimate 41 D–SNPs will need to submit a new Part C application; therefore, the currently approved total burden for one-time Part C applications will increase by 410 hours (10 hr × 41 D–SNPs) at a cost of $29,889 (410 hr × $72.90/hr).

The burden per MA organization for an initial Part D application for an MA–PD plan is currently approved by OMB under control number 0938–0936 (CMS–10137) at 6.41 hours for a compliance officer to review instructions and complete the application (including submission) at a cost of $467 (6.41 hr × $72.90/hr). Under this final rule, we estimate 41 D–SNPs will need to submit a new Part D application; therefore, the currently approved total burden for one-time Part C applications will increase by 263 hours (6.41 hr × 41 affected D–SNPs) at a cost of $19,173 (263 hr × 72.70/hr).

While we anticipate changes to the number of respondents and our active time estimates for the Part C and Part D applications, we will revise control numbers 0938–0935 (CMS–10237) and 0938–0936 (CMS–10137) for the 2025 plan year application. Because States will likely consult with CMS, MA organizations, and other stakeholders on whether and how to pursue this step toward integration and because of the timing of MA applications, bids, and contract execution, we believe the 2025 plan year application is the earliest date that the new policy in § 422.107(e) can be implemented by a State and MA organization. The CMS–10237 and CMS–10137 collection of information materials will be made available to the public for review/comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

We acknowledged in our proposal that there may be additional downstream collection of information impacts for new contracts related to Part C and D reporting and CMS monitoring at the contract level. For example, MA organizations would experience additional reporting to CMS, calculation of HEDIS measures, and administration of HOS and CAHPS surveys. We are uncertain of the extent of the additional burden incurred for reporting as a separate contract. We requested comments on these impacts for a new contract under an already existing MA organization and if they should be included in our estimates. We received no comments and are finalizing our estimates without including any additional collection of information impacts.

c. Integrated Member Materials

As described in section II.A.6.b. of this final rule, to provide a more coordinated beneficiary experience, at § 422.107(e) we are codifying a pathway by which States and CMS will collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Section 422.107(e)(1) establishes factual circumstances that would commit CMS to certain actions under paragraphs (e)(2) and (3).

We do not estimate any additional burden for States or plans to implement integrated member materials at § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. Since requirements imposed on the Federal Government are not subject to the PRA, we describe costs to the Federal Government's burden to develop integrated member materials in section V.D.3.c. of this final rule.

d. Conclusion

We did not receive any public comments on our proposed collection of information requirements and are finalizing these estimates as is with updated mean hourly wages.

5. ICRs Related to Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561) (CMS–10796, OMB 0938–1410)

The following changes will be submitted to OMB for approval under control number 0938–1410 (CMS–10796).

In § 422.561, we are expanding the universe of D–SNPs with unified grievance and appeals processes by revising the definition of the term ''applicable integrated plan,'' which establishes the scope of plans that are subject to the requirement to use those unified processes. Unified grievance and appeals processes were originally limited to FIDE SNPs and HIDE SNPs; however, after our implementation experience, we believe that there are models of integrated D–SNPs other than FIDE SNPs and HIDE SNPs that should be required to use, and are capable of using, the unified grievance and appeals processes.

We anticipate that additional D–SNPs will be implementing the unified grievance and appeals procedures under §§ 422.629 through 422.634 and that the D–SNPs impacted by this rule are D–SNPs in California with exclusively aligned enrollment, including those plans receiving Cal MediConnect members at the end of the California capitated FAI demonstration.

We estimate a one-time burden for each new applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under § 422.629. We anticipate this task will take a business operation specialist 8 hours at $76.20/hr. In aggregate, we estimate a one-time burden of 104 hours (8 hr × 13 D–SNPs) at a cost of $7,925 (104 hr × $76.20/hr).

While new D–SNPs will use the CMS–10716 denial notice under OMB control number 0938–1386 rather than the CMS–10003 MA denial notice under OMB control number 0938–0829, neither of the notices nor burden estimates would be revised as a result of this rule. As indicated previously, the rule's changes will be submitted to OMB under control number 0938–1410 (CMS–10796).

The CMS–10716 denial notice required under § 422.631(d)(1) includes information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights will be a new requirement for the impacted D–SNPs, we note that the timeframe for sending

[96] HPMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

a notice and the content of the notice are largely the same as the current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)); therefore, impacted D–SNPs are not incurring additional burden to send the notification. Setting out such burden would be duplicative.

We did not receive any public comments on our proposed collection of information requirements and are therefore finalizing our estimates as is but with updated mean hourly wages.

6. ICRs Related to Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this final rule, we are making a revision to which costs accumulate toward the MOOP limit, with the most significant impact being for dually eligible enrollees with cost-sharing protections under § 422.101 for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. As established in this final rule, all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid (such as because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals), will count towards the MOOP limit. This will ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan will pay 100 percent of the cost of covered Medicare Part A and Part B services. MA plans are currently tracking all costs accrued as part of preparing to submit an accurate plan benefit package bid (OMB control number 0938–0763 (CMS–R–262)); therefore, this provision does not add additional requirements or burden.

This final rule will update current guidance governing MA organization bid requirements, which are captured under our active OMB control number 0938–0763 (CMS–R–262). We do not foresee any new or revised burden that would arise from the changes. The non-PRA related burden can be found in section V.D.4. of this final rule.

We did not receive any public comments on regarding the collection of information requirements for this provision and are finalizing them without change.

7. ICRs Related to Network Adequacy (§ 422.116(a)(i)(ii) and (d)(7))

The following changes will be submitted to OMB for approval under control number 0938–1346 (CMS–10636).

In this rule we will require compliance with CMS's network adequacy standards for initial and service area expansion (SAE) applicants as part of the MA application process. Therefore, we will require that initial and SAE provider networks be submitted and reviewed in February instead of June (with plans being reviewed for the triennial review).

Consequently, the number of reviews and the amount of work is the same; rather, it is being re-distributed.

Comment: We did not receive any public comments specific to our proposed collection of information requirements. However, based on comments we received on our proposal to review applicants' provider networks during the time of application in mid-February of each year, we will modify the final regulation to include a change in our collection of information.

We received a number of comments that were not supportive of our proposal to require compliance with CMS's network adequacy standards for initial and SAE applicants as part of the MA application process. Commenters expressed concerns over the proposed timing for submission and review of provider networks, which they said would not allow sufficient time for MA organizations to build high-quality networks. Further, commenters said that our proposal would negatively impact negotiations with provider groups, give providers leverage to negotiate higher rates that would increase healthcare costs and reduce benefits. Commenters also suggested that our proposal would disproportionately impact smaller organizations working to expand to certain regional, rural, and medically underserved areas, thereby inhibiting competition among plans and ultimately limiting choice for beneficiaries; some of these commenters also expressed the view that the proposal would provide an unfair advantage to large health plans with a presence in these areas. Several commenters posited that our proposal would place a substantial administrative burden on MA organizations and on providers, and that establishing contracts with organizations takes a significant amount of time. Finally, a number of commenters asked CMS to consider allowing applicants to use Letters of Intent (LOIs) to contract with providers as a means to meet network adequacy standards, which would provide flexibility as they work to come into compliance for the coverage year.

Response: We appreciate the commenters' feedback regarding our proposal. As we noted in the proposed rule, we understand that requiring an applicant to establish a full provider network almost a year in advance of the contract becoming operational will be difficult. We also indicated that we previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational.

Therefore, based on the comments received, we will modify the regulation to allow applicants to use LOIs in lieu of signed provider contracts, at the time of application and for the duration of the application review. The LOI must be signed by both the MA organization and the provider with which the MA organization intends to negotiate. Further, as part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the contract year, the MA organization must be in full compliance with the section, including having signed provider and facility contracts in place of the LOIs.

We are not estimating the burden of updating systems to receive LOIs since this is done by CMS and its contractors and not subject to PRA requirements. We are not estimating the negotiations between plans and providers since these already occur, as would negotiations of LOIs. While there might be some increase in these negotiations, we do not have access to data on plan negotiations and believe that the assumption that the negotiations remain the same is valid.

There is an increase in burden because we will require applicants to submit the providers with whom LOIs have been entered into when submitting their MA application using CMS systems; previously, the LOIs were internal documents to the plan. We must be prepared that all applicants who may be requesting an exception to the network adequacy standards may submit LOIs. While there might be additional or less we have no way of ascertaining this and believe this a reasonable assumption.

As noted, applicants will use existing processes to submit the LOIs. Currently we have 468 MA applicants of which we expect about 45 percent to submit exceptions through CMS systems (CMS–10636, OMB 0938–1346). Thus, we assume 211 applicants (45 percent × 468

applicants) would submit an exception request. MA applicants are already collecting LOIs, and already submitting zipped files through our application and network adequacy review process. The extra burden to the applicants from this provision would be in gathering documents for the zip file and indicating whether there are LOIs. We are estimating that the extra burden of gathering forms and indicating a check on an application will take 5 minutes (0.083 hr). Therefore, the total burden of this provision is 18 hours (211 applicants × 0.083 hr) at a cost of $1,312 (18 hr × $72.90/hr for a compliance officer.)

8. ICRs Related to the Disclaimer for Preferred Pharmacy (§ 423.2267(e)(40))

The following disclaimer changes carry no burden. Section 423.2267(e)(40) would require Part D sponsors to insert CMS standard disclaimer on materials that mention preferred pharmacies. The burden associated with this requirement is the time and effort to copy the disclaimer on plan documents during document creation. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(c)(2). We believe that the time, effort, and financial resources to comply with the information collection requirements will be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practice.

This disclaimer is currently described in CMS's sub-regulatory guidance, the MCMG, and will be codified in this final rule. The disclaimer provides an important safeguard to Medicare beneficiaries enrolled in a Part D plan that only provide access to preferred cost-sharing through a limited number of pharmacies by alerting them that the preferred costs may not be available at the pharmacy they use, as well as providing information on how to access the list of pharmacies offering prescription drugs as a preferred cost in the beneficiary's area. We did not receive any public comments on our proposed collection of information requirements and are finalizing them without change.

9. ICRs Related to Member Identification Cards (§§ 422.2267(e)(30) and 423.2267(e)(32))

Member Identification Cards burden is exempt from the requirements of the PRA since the issuance of Medicare Identification Cards is a normal and customary practice throughout the insurance industry. Health plans, whether commercial, through Medicare or Medicaid, or Original Fee-For-Service issue cards that inform providers of the enrollee's insurance.

This final rule is a codification of previously issued sub-regulatory guidance in the MCMG defining standards for member identification cards issued by MA plans and Part D plan sponsors.

CMS created this sub-regulatory guidance to reduce Medicare beneficiary confusion through bringing consistency to member ID card requirements by applying standards so that ID cards from plan to plan contained the same information in the same locations.

The member identification card standard provided in the previously issued sub-regulatory guidance was created using an industry standard for ID cards; these industry standards reflected best practices and consequently plans found the previously issued sub-regulatory guidance implementable with minimal burden. Because of the minimal burden, plans will have no incentive to avoid using them. Additionally, we have received no enrollee complaints on member cards since issuing the sub-regulatory guidance.

Because of the reasons listed previously, we believe plans are following the standards described in this sub-regulatory guidance and therefore no further burden is imposed by codifying these standards in regulation.

We did not receive any public comments on our proposed collection of information requirements and are finalizing them without change.

10. ICRs Related to the Creation of a One-Page Multilanguage Insert (§§ 422.2267(e)(31) and 423.2267(e)(33)) (CMS–10802, OMB 0938–1421)

The following changes will be submitted to OMB for approval under control number 0938–1421 (CMS–10802).

The requirements finalized under §§ 422.2267(e)(31) and 423.2267(e)(33) will require that plans add in their postings or mailings of CMS required materials a one-page document written in the top 15 non-English languages in the U.S. informing enrollees that interpreter services are available at no cost.

We previously required plans to provide this document to enrollees. However, based on section 1557 of the Affordable Care Act, the Office for Civil Rights (OCR) created their own version. Because of the inherent duplication between CMS's MLI requirement and OCR's requirement, CMS issued an HPMS email on August 25, 2016, that removed the MLI requirement. OCR later vacated their requirement, leaving a gap. Consequently, we proposed to require that MA plans and Part D plan sponsors provide the one-page document.

Because the MLI will be standardized, plans will not be permitted to create their own version and will need to use the standardized template provided by CMS. In estimating the burden of this 1-page standardized document, we assume plans have retained their templates consistent with the record retention requirements at § 422.504(e)(4). Consequently, there is no burden to create the template, as plans will either use their existing templates or the standardized template that CMS will provide to new plans based on the previously-created MLI without change.

The cost of placing an extra page on the plan's web page is incurred by plans as part of their normal course of fluctuating business activities and hence excluded from the PRA (5 CFR 1320.3(b)(2)).

For beneficiaries who request a paper copy, this final rule requires that plans mail it to those beneficiaries along with other CMS required materials (§§ 422.2267(e) and 423.2267(e)). We believe it is reasonable to assume that adding one page (at 0.1696 ounces) to a bulk mailing cost is de minimis and therefore does not create additional postage costs.

Similar estimates have been made in previous final rules where we identified the major burden as paper and toner. We have checked the following assumptions of cost and beneficiary interest in receiving paper copies found in the April 2018 final rule (83 FR 16695), and found them to still be reliable for the purpose of this rule.

A 10-ream box (of 5,000 sheets) of paper costs approximately $50. Hence the cost per sheet is $50/5,000 sheets = $0.01 per page.

Standard toner cartridges which last for about 10,000 pages also cost $50. Hence the cost per sheet is $50/10,000 = $0.005 per page.

Thus, the total paper and toner cost is $0.015 per page.

As of September 2021, there are 52 million beneficiaries enrolled in MA PD or stand-alone PDP plans.[97]

Of these 52 million beneficiaries we estimate that 40 percent or 20,800,000 beneficiaries (52 million beneficiaries × 0.40) will request paper copies.

[97] *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-09.*

It follows that the aggregate cost of providing one extra sheet of paper is $312,000 (20,800,000 enrollees × $0.015/page).

There is no labor cost for providing one extra sheet of paper.

We solicited stakeholder input on all assumptions including the estimate that 40 percent of enrollees request paper copies and that the major costs are paper and toner.

Comment: We received comments indicating generally that our estimate of the burden to plans was incorrect. A commenter indicated our estimate of the burden was incorrect without providing any specifics on the nature of the alleged error or its impact on the burden calculation. Another commenter indicated that our estimate of the burden was too low, but they did not indicate to what degree or in what way they felt we had miscalculated.

Response: As the comments did not provide specific parameters as to how our burden estimate is inaccurate, we decline modification of estimates based on the comment. On review, we believe our assessment of the burden on plans is accurate. Regardless, we also believe the burden on plans is acceptable considering the vital nature of the MLI. Additionally, we expect that plans consider the burden acceptable as the MLI improves awareness of health issues; and as plans are committed to the health of their members, they support the MLI as is a bridge to education and awareness of health and health insurance issues.

We did not receive any other comments on our proposed collection of information requirements and are finalizing them without change.

11. ICRs Related to Third-Party Marketing Organizations (TPMOs) Agent (§§ 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2274(g))

Sections 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2275(g) will require MA organizations and Part D sponsors to insert a CMS standard disclaimer on materials created by Third Party Marketing Organizations.

The burden associated with this requirement will be the time and effort to copy the disclaimer on marketing materials during document creation. The disclaimer is a standardized, required material. In this regard we believe that the disclaimer is not subject to the requirements of the PRA because it does not constitute a ''collection of information.'' Instead, the disclaimer is a ''public disclosure'' of information originally supplied by the Federal Government to the recipient (5 CFR 1320.3(c)(2)).

CMS did not receive any other comments on our proposed collection of information requirements and are finalizing them without change.

CMS received no comments on the estimates for this proposal and therefore are finalizing this provision estimate without modification.

12. ICRs Related to the Medicare Medical Loss Ratio (MLR) Reporting Requirements (§§ 422.2460 and 423.2460) (CMS–10476, OMB 0938–1232)

The following changes to the Medicare MLR reporting requirements will be submitted to OMB for approval under control number 0938–1232 (CMS–10476).

In section II.G.2. of this final rule, we note that under current §§ 422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors are required to report only that the contract is non-credible. In this rule, our amendments to §§ 422.2460 and 423.2460 would increase the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, such as the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410 or § 423.2410.

In estimating impact, we initially focus on hourly burden. Once the hourly burden of this final rule is established, we calculate the per contract and aggregate hourly and dollar burden. The reason for this approach is that the estimates of hourly burden have undergone several changes; focusing on them first provides a clearer exposition.

The following four regulatory sources, final rules and PRA packages, are used as a source for items estimated. These are presented here with brief outlines of their contributions which will be detailed below. (i) The information collection that was previously approved by OMB under 0938–1232 (CMS–10476) in connection with the requirements finalized in the May 2013 Medicare MLR final rule, CMS estimated that, on average, MA organizations and Part D sponsors will spend 47 hours per contract on Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting internal review, submitting the reports to the Secretary, and conducting internal audits. (ii) This 47-hour figure was also used in the April 2018 final rule (83 FR 16701) to estimate the reduction in burden resulting from that rule's revisions to the MLR reporting requirements that apply with respect to MLR reporting for contract year 2018 and subsequent contract years. (iii) The June 2020 final rule (84 FR 33796 to 33850), added a deductible-based adjustment to the MLR calculation for MA medical savings account (MSA) contracts. (iv) The current final rule, which introduces three changes: Automation of the MLR reporting for MA organizations including the MSA reporting requirement, reinstatement of detailed MLR reporting requirement used in 2014–2017, and addition of data fields related to expenditures on supplemental services.

Five items must be estimated to perform the impact analysis. They are presented in Table 5. Table 5 indicates if these items have undergone change for this final rule.

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TABLE 5: SUMMARY OF KEY ITEM ASSUMPTIONS USED IN CALCULATIONS

Item	Information Collection previously approved under OMB Control Number 0938-1232; April 2018 final rule	June 2020 rule	Final Rule
Total assumed administrative burden related to MLR form used as a starting point and then apportioned into i) the burden for the completion of the form and ii) other administrative burden. See next three rows.	47 hours; 36.75 hours	36.75055 hours	61.1 hours
Burden for completion of MLR forms (There are three forms: (1) the 2014-2017 form, (2) the 2018-current form, (3) the form that will be used starting in 2023 (under this final rule)	(1) 11.5 hours for completing the 2014-2017 form. (2) 0.5 hour for completing the 2018 form.	(2) 0.5 hour for completing the 2018 form.	Discussed below. Compared with the 2014-2017 form, there is an increase of 33.3 percent of fields for MA organizations; there is a 5 percent increase for sponsors of stand-alone Part D contracts. The 11.5 estimate presented in the April 2018 rule and included in the June 2020 rule burden estimate was classified as an error in the proposed rule (and this final rule) and has been corrected (for purposes of estimating the burden increase) to 10.75 hours. (3) 24.85 hours for completing the form that will be used starting in 2023 (under this final rule)
Other administrative burden	This is a derived calculation. It equals total administrative burden minus burden for completion of forms		
Burden for MSA deductible factor calculation	Not present	Introduced in June 2020 final rule. The annual burden was estimated to be 0.00055/hr.	Eliminated in proposed rule and this final rule
Average number of contracts	601		

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We next present more detailed discussion of some of these assumptions.

Number of contracts: Our analysis of the estimated administrative burden related to the MLR reporting

requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. For contract years (CYs) 2014 to 2020, the average number of such contracts is 601. The total number of MA and Part D contracts is relatively stable year over year varying from 533 to 691 during CYs 2014–2020, such that we are applying the 601 average in this rule's burden estimates.

Total hourly burden related to MLR: It is necessary to estimate the total effort (time) related to the Medicare MLR requirements that applied with respect to MLR reporting for contract years 2014 through 2017. In the information collection request that was previously approved by OMB under 0938–1232 (CMS–10476), CMS estimated the total time spent on MLR reporting to be 47 hours. The April 2018 final rule subsequently divided this 47 hour estimate into two components: Time to complete the MLR form and time spent on other administrative tasks related to MLR reporting.

Time to complete the MLR form: In the April 2018 final rule (83 FR 16701), we estimated that it would take an MA organization or Part D sponsor 11.5 hours to complete the MLR reporting form that was used to collect MLR data for CYs 2014 through 2017. We explained that we developed this estimate by considering the amount of time it would take an MA organization or Part D sponsor to complete *each* of the following tasks:

- Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions.
- Draft narrative descriptions of methodologies used to allocate expenses.
- Perform an internal review of the MLR report form prior to submission.
- Upload and submit the MLR report and attestation.
- Correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.

In 2018, we finalized a less detailed form which we estimated takes 0.5 hours to complete.

The calculations for hourly burden per contract that were included in the April 2018 final rule are summarized in Table 6. These calculations do not reflect the corrections to the April 2018 rule that were taken into account in our burden estimate for the proposed rule.

TABLE 6: TIME PER CONTRACT USED IN APRIL 2018 FINAL RULE (HOURS)

Row ID	Item	Estimate	Notes
(1)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	Estimate used in former approved Information Collection Request that included MLR form used for CYs 2014-2017
(2)	Original estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	11.5	Assumption in April 2018 final rule about amount of time needed to complete MLR form used for CYs 2014-2017
(3)	Burden for administrative tasks other than completing MLR form (hr)	35.5	(3) = (1) - (2)
(4)	Estimate of burden for completing current MLR form (hr)	0.5	Assumption in April 2018 final rule
(5)	Total administrative burden for current MLR form (hr)	36	(5) = (3) + (4)

The following explanations apply to the rows in Table 6:

Row (1): The 47-hour figure, as explained in the opening paragraphs of this ICR, is CMS's estimate for the total amount of time MA organizations and Part D sponsors will spend per contract on Medicare MLR reporting when the MLR was reported using the MLR form for CYs 2014 through 2017, including: Collecting data, populating the MLR reporting form, conducting internal review, submitting the report to the Secretary, and conducting internal audits.

Row (2): The 11.5-hour burden is the portion of the burden in Row (1) that the April 2018 final rule assumed was associated with completing the MLR form used for CYs 2014 through 2017. This burden is discussed in the paragraph immediately preceding Table 6.

Row (3): 35.5 hours, the administrative burden associated with the MLR requirements, excluding the April 2018 final rule's estimate of the burden for completing and submitting the MLR form used for CYs 2014 through 2017. This number represents the difference between total per contract burden, 47 hours, and the form burden per contract, 11.5 hours.

Row (4): Estimated burden to complete the current MLR data form, which is vastly simplified and is estimated to take only a half-hour to complete.

Row (5): The total burden per contract, as written in the April 2018 final rule, and as adjusted for the current number of contracts is 36.00 (35.5 hours non-form burden + 0.5 hours current form burden).

However, we cannot use Table 6 as a basis for comparing the burden of this final rule with the current burden. The reason we cannot use Table 6 is because the 11.5 hours (Row (2)) in Table 6 was corrected in the proposed rule. As indicated in Tables 5 and 6, the other Administrative burden is a calculated number equal to the difference between the total burden of 47 hours and the

burden of filling out the form (Row (3)). Consequently, if Row (2) changes, then Row (3) must change also. We next discuss the revisions of the April 2018 estimates just summarized in Table 6.

In the proposed rule, we explained that after further consideration, we believe that the April 2018 final rule overstated the burden of completing the detailed MLR reporting form because it did not take into account the number of MA organizations and Part D sponsors that were actually required to provide explanations for suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report. Unlike the first four tasks previously listed (the first four of the bullets immediately listed prior to Table 6), the need to correct or provide explanations for errors and omissions discovered by CMS or our contractor during desk reviews and estimated at 11.5 hours (Row (2)) was not applicable to all plans when our detailed MLR data reporting requirements were in effect.

Based on the percentage of contracts per contract year (for years 2014 through 2017) for which the annual MLR filing was flagged for potential errors during desk reviews, the number of MA organizations and Part D sponsors that were required to correct or explain suspected errors during desk reviews, and a review of the correspondence between such organizations or sponsors and CMS or our contractor, we estimated the last task previously listed (to correct or provide explanations for suspected errors or omissions flagged in desk reviews) would take an MA organization or Part D sponsor an average of 3 hours per affected contract, depending on the number and complexity of issues that required additional explanation, whether the MA organization or Part D sponsor had to recalculate any of the figures included in its original MLR submission, and whether the MA organization or Part D sponsor had to submit a corrected MLR Report to address any of the errors or omissions in its original submission.

Table 7 presents a revision of Table 6 with the primary change being replacing 11.5 (Row (2) in Table 6) with 10.75 (Row (7) in Table 7), with the other rows following by computation. Table 7 also differs from Table 6 is the addition of the per contract burden of calculation of the MSA deductible factor. This is explained in the narrative to Table 7.

This refinement to our prior 11.5-hour time estimate does not affect our estimate that MA organizations and Part D sponsors spent 47 hours per contract under the MLR reporting requirements in effect for CYs 2014 through 2017 (Row (1) in Table 6) which as we have noted was an aggregate number estimated by CMS in the information collection that was previously approved by OMB under control number 0938–1232 (CMS–10476). Instead, it causes the estimated time to complete the detailed MLR reporting form to decrease from 11.5 hours to 10.75 hours (Row (2) in Table 6 and Row (7) in Table 7), with the remaining administrative tasks, a derived calculation, now estimated as taking the other 36.25 hours (47 hours − 10.75 hours) (Row (8) in Table 7).

TABLE 7: TIME PER CONTRACT IN APRIL 2018 FINAL RULE REVISED (HOURS)

Row ID	Item	Estimate	Notes
(6)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	(1)
(7)	Revised estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	10.75	Reduced from original 11.5 hr estimate
(8)	Burden for administrative tasks other than completing MLR form (hr)	36.25	(8)=(6)-(7)
(9)	Estimate of burden for completing current form (hr)	0.5	(4)
(10)	Burden for calculation of MSA deductible factor (hr)	0.00055	Burden per contract of calculation of MSA deductible factor. This is explained in the narrative below.
(11)	Total administrative burden for current MLR form (hr)	36.75055	(11)=(8)+(9)+(10)

We next explain row (10), calculation of the deductible factor. In the June 2020 final rule, CMS estimated that it would take 5 minutes (1/12 hour) to calculate and verify the deductible factor for an MSA contract. At the time of the 2020 rule, there were 8 MSA contracts. As of 2021, there are only 4 MSA contracts. However, the calculations presented in Table 7 are per contract, not aggregate. Thus, the hourly burden for calculation of the MSA

deductible factor adjusted for the number of current contracts is 0.00055 hours (1/12 hour per contract × 4 MSA contracts divided by 601 total contracts). We round to 5 decimal places because if we had rounded to two decimal places the burden would be 0 (zero).

This final rule finalizes three items affecting per contract hourly burden that were introduced in the proposed rule. These changes are summarized in Table 9 which will be referred to throughout the following discussion of the three changes. First, as noted in section II.G.3. of this final rule, in connection with the changes to the reporting requirements CMS is adopting in this final rule, we expect to resume development of the MLR reporting software, and to update the data collection fields and built-in formulas so that the MLR reporting software calculates the MLR consistent with all amendments to the MLR regulations that CMS has finalized since contract year 2017. In making these updates, CMS is revising the programming of the MLR reporting software so that it automatically calculates and applies the appropriate deductible factor for MA MSA contracts, as determined under § 422.2440. Because MA organizations would no longer be responsible for calculating the deductible factor, the burden associated with performing that calculation will be eliminated. Thus Row (19) in Table 9 is 0 contrasting with Row (10) in Table 7 which had a positive amount.

Second, as discussed in section II.G.2. of this final rule, CMS is finalizing our proposal to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017. This changes the 0.5 hour estimate in Rows (4) and (9) to 10.75 hours (Row (18)).

Third, we are finalizing our proposal to require a detailed MLR report that provides details on several categories of data and costs (for example, the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS) and also permits CMS to break down the general categories and require additional details or line items to be included in the report. As discussed in section II.G.3. of this final rule, to collect this information, we are adding additional fields to the MLR Report template in which MA organizations will enter their total expenditures for different types or categories of supplemental benefits. We are also adding narrative fields in which users will describe the methodologies used to allocate supplemental benefit expenditures.

In total, we estimate that the addition of these fields, as well as an information-only field in which MA organizations and Part D sponsors will enter the low-income cost-sharing subsidy amount that they deducted when calculating the amount of prescription drug costs to include in the MLR report, will increase the number of fields that will require user input and validation by approximately one-third, or 33.3 percent. We believe this increase would cause a proportional increase in the amount of time needed both to complete and submit the MLR Report to CMS, and to perform the data collection activities that make up the remaining portion of the 47 hours per contract that we previously estimated MA organizations and Part D sponsors would spend on tasks related to the MLR reporting requirements.

However, because the new supplemental benefits fields do not affect the MLR reporting burden for sponsors of standalone Part D contracts, we calculate the MLR reporting burden separately for MA contracts and standalone Part D contracts. Thus, we estimate the burden to stand-alone Part D contracts would only increase 5 percent in contrast to the 33.3 percent increase for MA contracts and Part D sponsors estimated in the previous paragraph. This is summarized in Row (12) of Table 8. To aggregate this increase on a per-contract level, we take a weighted average of the 33 percent increase and the 5 percent increase. The weights correspond to the percentage of contracts that represent MA contracts (about 89 percent) and standalone Part D contracts (about 11 percent). This aggregate net increase per contract is 29.92 percent (89% × 33% + 11% × 5%). The computations are presented in Table 8. It is simpler to use one aggregate figure (29.92 percent) for all contracts rather than estimate each contract type separately and then adding them together. This weighted average on Row (14) in Table 8 is used to estimate the increased burden finalized in this rule of filling out MLR forms as calculated in Row (21) in Table 9.

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TABLE 8: CALCULATION OF (WEIGHTED) AVERAGE INCREASE IN TIME PER CONTRACT

Row ID	Contract Type	Percent of contracts	Increase for new fields	Product of Increase and Percent (weight) of contract type	Notes
(12)	Stand-alone prescription drug contracts	11%	5%	0.55%	Rounded to 4 decimal places. Rounding to two decimal places would make this 1, a misleading increase.
(13)	MA (including MA-PD and MSA) contracts	89%	33%	29.37%	Rounded to 4 decimal places for consistency with previous row.
(14)	Aggregate burden increase per contract			29.92%	(14)=(12)+(13)

TABLE 9: BURDEN (AGGREGATE and PER CONTRACT)

Row ID	Item	Burden	Notes
(15)	Total time (hr) per contract	47	(6)
(16)	Revised (2018 rule) time (hr) per contract for then-current detailed form	10.75	(7)
(17)	Time (hr) per contract for non-form items	36.25	(17)=(8) or (17)=(15)-(16)
(18)	Per contract burden for return to detailed form used for CYs 2014-2017	10.75	Removal of current form; return to form used for CYs 2014-2017 (see row (7))
(19)	Per contract burden for calculation of deductible factor for MSA contracts (hr)	0	Software now automatically calculates the MSA deductible factor
(20)	Per contract revised time (hr) for return to detailed form used for CYs 2014-2017 and removal of calculation of MSA deductible factor	47	(20)=(17)+(18)
(21)	Per contract time (hr) for detailed form with new fields, this rule	61.1	(21)=(20)+(14)*(20)
(22)	Current per contract time (hr)	36.75055	(22) = (11)
(23)	Average increase time (hours/contract)	24.34945	(23) = (21) - (22)
(24)	Wage/hr	156.66	Wage Table
(25)	Per contract cost ($) for detailed form, this rule, with new fields	$3,815	(25)=(24)*(23)
(26)	Number of current contracts affected by MLR provisions	601	Estimate explained in opening paragraph of this ICR
(27)	Aggregate increase in time (hr), all contracts, with new fields, this rule	14,634	(27)=(26)*(23)
(28)	Aggregate cost ($), all contracts, with new fields, this rule	$2,292,562	(28)=(27)*(24)

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Table 9 incorporates these three changes—removing the deductible factor calculation burden, reinstating the form used for MLR reporting for CYs 2014 through 2017, and increasing the fields in the form—to arrive at a final increased hourly burden per contract, and then calculates dollar burden per contract as well as aggregate burden for all contracts. The following presents further information about the rows in Table 9 as compared to Table 7.

- Rows (15)–(17) are identical to Rows (6)–(8). This provides the per-contract administrative hours on non-form items connected with the MLR provisions before adding the form-related burdens.
- Row (18): The 0.5 hours in Row (9) is replaced by the 10.75 hours in Row (16) since this final rule requires returning to the detailed form used for MLR reporting for CYs 2014 through 2017 whose cost is estimated in Row (7).
- Row (19): Row (10), the time for calculation of the MSA deductible factor, is replaced with 0 hours, since the changes CMS is finalizing would entail having CMS-developed software automatically calculate and apply the deductible factor.
- Row (20): The total hourly burden per contract, 47 hours, reflecting returning to the detailed form used for contract year 2014 through 2017 MLR reporting and removal of calculation of the MSA deductible factor (but not yet reflecting additional fields) is obtained by adding 10.75 (form burden) + 36.25 (non-form burden), (Rows (17) and (18)).
- Row (21): The total hourly burden per contract, 61.1 hours under the

requirements we are adopting in this final rule, is obtained by increasing the 47 hours (Row (20)) by 29.92 percent, which is the weighted effect of adding new fields (Row (14)) (61.1 = 47 + 29.92 percent × 47).

• Row (22): The current contract burden of 36.75055 hours is obtained from Row (11). The five decimal places assure that the effect of the provision on MSAs is not removed.

• Row (23): The average increase in time under the requirements we are finalizing of 24.34945 is obtained by subtracting from the total burden under the regulation requirements we are finalizing of 61.1 hours on Row (21) the current-form burden of 36.75055 hours on Row (22).

• Row (25): The increased contract cost ($) $3,815 on Row (25) is obtained by multiplying the average increase in time (hours) of 24.34945 on Row (23) by the wages ($156.66/hr) on Row (24).

• Row (26): The total number of contracts is presented in Table 5

• Row (27): The average increase in time (hours) across all contracts of 14,634 is obtained by multiplying the 601 contracts (Row (26)) by the per contract increase in time (hours) of 24.34945 on Row (23).

• Row (28): The aggregate increase in cost ($) across all contracts, $2,292,562 is obtained by multiplying the increase in time (hours) of 14,634 on Row (27) by the wages per hour on Row (24).

We estimate that MA organizations and Part D sponsors will incur minimal one-time start-up costs associated with developing processes for capturing the necessary data, as they should already have been allocating their expenses by line of business and contract in order to comply with our current regulations regarding the calculation of the MLR, and they should already have been tracking their supplemental benefit expenditures for purposes of bid development. We estimate that MA organizations and Part D sponsors will incur ongoing annual costs relating to data collection, populating the MLR reporting form, conducting an internal review, submitting the MLR reports to the Secretary, and conducting internal audits.

Table 10 summarizes the relevant calculations as one combined line item.

TABLE 10: BURDEN ASSOCIATED WITH THE MLR PROVISIONS

Respondent	Number of Respondents	Responses per Respondent	Time per Response (hours)	Total Annual Time (hours)	Hourly Labor Cost ($/hr)	Total Cost ($)
Contracts subject to MLR reporting requirement	601	1	24.34945	14,634	$156.66	$2,292,562

The average burden per contract as given on Row (25) of Table 8 is $3,815. We note that this is a weighted average. Stakeholders may be interested in a more careful analysis based on contract type. We do this for 3 types of contracts.

MA MSA contracts have reduced burden since the new software automatically calculates the deductible factor and uses that to adjust the applicable credibility factor, relieving them of the need to perform this calculation and adjustment on their own.

For each MA contract (including MA–PD and MA MSA contracts), we estimate, on average, 25.92 hours of additional burden at an additional cost of $4,061. Row (11) (which excludes the burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. (The removal of the 0.00055 hours has negligible effect and is appropriate for the majority of contracts which are non-MSAs). Row (20) shows that the new burden without considering the additional fields is 47 hours. Row (13) shows that this would result in 62.67 hours total burden (47 hours × 1.33 due to increased fields). Comparing the 62.67 total burden under the MLR reporting requirement we are adopting in this final rule with the 36.75 hours under the reporting requirements that have been in effect since contract year 2018 shows an increase time of 25.92 hours (62.67 − 36.75) at a cost of $4,061 (25.92 hours × $156,66/hr).

For Part D contracts, we estimate 12.6 additional hours of burden at an additional cost of $1,974. As in the preceding analysis for MA contracts, Row (11) (which excludes burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. Row (20) shows that the new burden without taking into effect the new fields is 47 hours. Row (12) shows a 5 percent increase for new fields for Part D contracts, such that this would result in a total burden of 49.35 hours (47 hours + 47 hours × 5 percent). Thus, there is an additional hour burden of 12.6 hours (49.35 hours − 36.75 hours) at an additional cost of $1,974 (12.6 hours × $156.66/hr) per contract.

As indicated above, the total increased impact of finalizing the MLR provision is presented in Table 10.

We did not receive any comments on our proposed collection of information requirements and are finalizing them without change.

13. ICRs Related to Pharmacy Price Concessions in the Part D Negotiated Price (§§ 423.100 and 423.2305) (CMS–10174, OMB 0938–0982)

The requirement and burden for Part D Sponsors to implement the proposals related to pharmacy price concessions that we are now finalizing, as discussed in section II.H. of this final rule will be submitted to OMB for approval under control number 0938–0982 (CMS–10174), as needed. Below we discuss in greater detail the burden associated with the requirements we are finalizing.

Revisions to §§ 423.100 and 423.2305 will require that Part D sponsors apply all pharmacy price concessions to the point of sale price in all phases of the Part D benefit. Under this rule, beneficiaries will see lower prices at the pharmacy point-of-sale and on Plan Finder beginning immediately in the year the policy will apply, 2024. We anticipate that the change will require that Part D sponsors make certain system changes related to the calculation of the amounts they report in one or two fields in the PDE data collection form.

In the NPRM we only estimated the impact of annual costs for PDE Data transmission. Although we received no

external comments on our burden estimates, we made two changes from the NPRM. First, we anticipate that this provision will cause sponsors to incur both one-time costs for updating software, and annual costs for PDE Data transmission. Second, our estimates of PDE data transmission used an estimate of a $35.50/hr cost for electronic submission. This is incorrect and should be $17.75/hr.

Update of Software: The systems for submitting PDE transmission are already in place as required by the regulations. A software update is required to deal with transmitting data at the time of sale. We believe it reasonable that this software update will be done at the parent organization level rather than the contract level. Based on internal CMS data, currently there are 298 parent organizations. The burden of update requires that 2 software developers will each spend 20 hours (2 and one half days) performing the necessary designs. Therefore, the aggregate burden across all parent organization is 11,920 hours (2 software developers × 20 hr a programmer × 298 parent organizations) at a total cost of $1,386,773 (11,920 hr × 116.34/hr). The burden per parent organization would be 40 hours (20 hr × 2 software developers) at a cost of $4,654 (40 hr × $116.34/hr).

PDE Data Submission: The calculations discussed in the narrative are presented in Table 11. The number of prescription drug events (PDE) for 2020 is 1.5 billion (Row C). The average number of Part D contracts for the past 3 years (2019–2021) is 856 (Row B). To compute the average number of responses per respondent, that is, the number of PDEs per contract, we divide the average number of PDEs per year (Row C) by the average number of contracts (Row B). This computation leads to an average of 1,752,336.449 PDEs/contract (Row D (1.5 billion divided by 856)). The extra decimal places listed in Row D and other rows are to assure consistency in two methods at arriving at the final burden. A similar computation shows that the average number of PDEs per Part D enrollee is 30.5047 (1.5 billion PDE (Row C) divided by 49,229,626 enrollees (as of November 2021) (Row A).

Since our regulations require Part D sponsors to submit PDE data to CMS that can be linked at the individual level to Medicare Part A and Part B data in a form and manner similar to the process provided under § 422.310, the data transaction timeframes will be based on risk adjustment and prescription drug industry experiences. Moreover, our PDE data submission format only supports electronic formats.

The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records (Row F). The drug industry further estimates that on average it costs $17.75/hr (for 2020) to process PDEs (Row E).

Using these numbers, we can compute individual contract and aggregate burden.

It would take 3.5047 hours (Row G) on average for each respondent (contract) to process its 1,752,336.449 PDEs at a rate of 500,000 per hour (1,752,336.449 PDEs per contract (Row D) divided by 500,000/hr (Row F). The aggregate hours to process all 1.5 billion claims is therefore 3,000 hours (Row H) (3.5047 hours/contract (Row G) × 856 contracts (Row B)).

The average cost per contract (Row I) is $62.2084 hours (3.5047 hours (Row G) × $17.75/hr (Row E)). The ongoing cost for all contracts (Row J) is therefore $53,250, which can be obtained either by multiplying total hours (3,000 (Row H)) by cost per hours(17.75/hr (Row E)) or by multiplying the cost per contract ($62.2084 (Row I)) by the number of contracts (856 (Row B)).

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TABLE 11: ESTIMATED ADMINISTRATIVE COSTS RELATED TO SUBMISSION OF PRESCRIPTION DRUG EVENT (PDE) DATA

Row ID	Item	Estimate	Source/Derivation	Description
A	Part D Enrollees	49,229,626	Internal CMS data	Number of Part D Enrollees as of November 2021
B	Number of respondents	856	Internal CMS data	Average Number of Contracts 2019-2021
C	Total responses	1,500,000,000	Internal CMS data	PDEs per year
D	Average responses per respondent	1,752,336.449	(C) / (B)	Average PDEs per contract
E	Cost per hour (Non labor)	$17.75/hr	Drug industry's estimated cost/hr of electronic processing	Cost/hr of processing PDEs electronically
F	Electronic PDEs processed per hour	500,000	Drug industry's estimated average processing volume per hour	Number of Electronic PDEs processed per hour
G	Hours/respondent	3.5047	(D) / (F)	Number of hours needed to process one contract's PDEs
H	Aggregate hours	3,000	(G) x (B)	Total hours to process all contracts
I	Cost per respondent	62.2084	(G) x (E)	Cost per contract to process PDEs
J	Total cost all contracts	53,250	Either (H) x (E) or (I) x (B)	Total cost for all contracts

The aggregate burden for the provision is $1,440,023 in the first year ($1,386,773 for software updates plus $53,250 for transmission costs) and $53,250 in subsequent years.

C. Summary of Finalized Information Collection Requirements and Associated Burden Estimates

TABLE 12. SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Section in Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondent	Number of Respondents	Responses per Respondent	Total Responses	Time per Respondent (hours)	Total Time (hours)	Hourly Labor Cost ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.107(f)	Solicit committee members	0938-1422 (CMS-10799)	D SNPS	310	1	310	40	12,400	76.20	944,880	944,880
422.101	Update HRA System	0938-1422 (CMS-10799)	SNP Parent Organizations	47	1	47	3	141	116.34	16,404	0
422.107(e)	Update Contracts with D-SNPs	0938-1410 (CMS-10796)	State	12	1	12	24	288	142.34	20,497*	0
422.107(e)	Update Contracts	0938-0935 (CMS-10237)	D SNPS	60	1	60	8	480	142.34	68,323	0
422.107(e)(1)	Part C Contracts with only D SNPS	0938–0935 (CMS-10237)	D SNPS	41	1	41	10	410	72.90	29,889	0
422.107(e)(1)	Part D Contracts with only D SNPS	0938–0936 (CMS-10137)	D SNPS	41	1	41	6.41	263	72.90	19,173	0
422.561	Update Contracts	0938-1410 (CMS-10796)	D SNPS	13	1	13	8	104	76.20	7,925	0
422.116(f)	Update Network Adequacy	0938-1346 (CMS-10636)	MA Contracts	211	1	211	0.0833	18	72.90	1,312	1,312
422.2267(e)(31) and 423.2267(e)(33))	1 pager multi-language insert	0938-1421 (CMS-10802)	MA Plans and Part D Sponsors	961	21,644	20,800,000	n/a	a/a	n/a	312,000 (non-labor)	312,000 (non-labor)
422.2460 and 423.2460	MLR	0938-1232 (CMS-10476)	MA and Part D Contracts	601	1	601	24.34945	14,634	156.66	2,292,562	2,292,562
423.100 and 423.2305	Part D Pharmacy Price Concessions (ongoing costs of reporting PDEs)	0938-0982 (CMS-10174)	Part D Sponsors Contracts	856	1,752,336.449	1,500,000,000	3.5047	3000	17.75	53,250	53,250
423.100 and 423.2305	Part D Pharmacy Price Concessions (one-time system change costs)	0938-0982 (CMS-10174)	Part D Sponsors Parent Organizations	298	1	298	40	11,920	116.34	1,386,773	0
	Totals			1,271***	1,773,990	*Varies*	*Varies*	43,658	*Varies*	5,152,988	3,604,004

NOTES:

*This number is halved because the Federal Government covers half the cost.

**Includes MA only, MA PD, and PDP plans.

*** To avoid double counting, the 1,271 is the sum of distinct parent organizations (298), distinct contracts (961) and distinct states (12) Note that the 961 contracts already include specific types of contracts such as D-SNPs. Similarly, the 298 parent organizations include specific types of parent organizations such as those for D-SNPs.

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V. Regulatory Impact Analysis

A. Statement of Need

This final rule will revise the MA and Part D program regulations to improve transparency in, and oversight of, these programs and to revise regulations to improve the integration of Medicare and Medicaid programs for individuals enrolled in dual eligible special needs plans (D–SNPs). This final rule will also revise regulations related to MA and Part D plans, D–SNPs, other special needs plans, and cost contract plans. Additional revisions will implement changes related to requirements during disasters or public emergencies, past performance, MLR reporting, pharmacy price concessions, marketing and communications, Star Ratings, and network adequacy.

Through provisions that apply to D–SNPs, we intend to improve beneficiary experiences by amplifying the voices of dually eligible individuals in health plan governance and operations by requiring an enrollee advisory committee and requiring assessment of certain social risk factors. Additionally, our final rule will improve partnership with States through better Federal-State collaboration on oversight and performance improvement activities and establishing new pathways for CMS and States to collaborate to integrate care for dually eligible individuals.

The past performance proposals hold plans more accountable for their performance under MA and Part D and protect the best interest of the Medicare program by preventing those with poor past performance from entering new MA or Part D applications or service area expansions. The Star Ratings provisions allow CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey; due to the COVID–19 PHE in place nationwide during 2020, applying the 60 percent rule in the current regulations would result in removal of all contracts from threshold calculations and CMS would be unable to calculate ratings for these three measures. In sections II.D.3. and II.D.4. of this final rule, we are also responding to comments about and finalizing Star Ratings provisions from the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC without modification: §§ 417.472(i) and (j), 422.152(b)(6), 422.166(a)(2)(i), (f)(1)(i), (g)(3), (i)(11), and (j)(1)(i) through (iv), 422.252, 423.182(c)(3), and 423.186(a)(2)(i), (f)(1)(i), (g)(3), (i)(9), and (j)(1)(i) through (iii). We are not finalizing the following provisions in the March 31st COVID–19 IFC: §§ 422.164(i), 422.166(j)(1)(v) and (j)(2), 423.184(i), and 423.186(j)(1)(iv) and (j)(2).

Due to a rule change that took effect with CY 2018 MLR reporting, MA organizations and Part D sponsors only submit to CMS the MLR percentage and amount of any remittance that must be repaid to CMS for failure to meet the 85 percent minimum MLR requirement. CMS is finalizing our proposal to change our regulations to reinstate the former requirement for MA organizations and Part D sponsors to submit the underlying information needed to calculate, and verify the accuracy of, the MLR and remittance amount. We believe reinstating this detailed data submission requirement and the desk review process will allow us to detect errors in the MLR calculation which can result in significant losses to the Government.

We are deleting the existing definition of ''negotiated prices'' at § 423.100 and adopting a new definition for the term ''negotiated price'' at § 423.100, which we define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). This provision will reduce out-of-pocket prescription drug costs, improve price transparency and market competition under the Part D program. As discussed in the proposed rule, based on stakeholder feedback and sponsor-reported DIR data, we understand that the share of pharmacies' reimbursement that is contingent upon their performance under such arrangements has grown steadily each year. When pharmacy price concessions received by Part D sponsors are not reflected in lower drug prices at the point of sale and are instead used to reduce plan liability, beneficiaries generally see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing. Thus, beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

President Biden's Executive Order (E.O.) 14036, ''Promoting Competition in the American Economy'' (86 FR 36987), section 5 (''Further Agency Responsibilities''), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry. Because variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, and given the programmatic impacts laid out above and the charge from the E.O., CMS proposed changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point of sale.

We are clarifying our regulations regarding the special requirements for disasters and emergencies at § 422.100(m) to address stakeholder concerns about the end of a disaster or emergencies and to codify previous guidance. We also are finalizing the proposed updates to them to allow smoother transitions for enrollees who during a disaster or emergency may have been obtaining services from out-of-network providers.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also

referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). While the total annualized costs for this rule are estimated at $3.1 million a year, as indicated in Table 20, the net transfers from the Trust Fund to enrollees and manufacturers exceed $100 million annually. Therefore, based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, 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, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2022, that threshold is approximately $165 million. This rule will not mandate on an unfunded basis any requirements for State, local, or tribal governments nor would it result in expenditures by the private sector meeting that threshold in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Under Executive Order 13132, this final rule will not significantly affect the States. It follows the intent and letter of the law and does not usurp State authority beyond what the Act requires. This rule describes the processes that must be undertaken by CMS, the States, and D–SNPs in order to implement and administer the requirements of the MA program. In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. As of November 2021, there are 962 contracting organizations with CMS (which includes MA, MA–PD, and PDP contracts). Additionally, there are 55 State Medicaid agencies and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). A reasonable maximal number is 1,500 total entities who will review this rule We note that other assumptions are possible. We assume each organization will designate two people to read the rule.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $114.24 per hour, which includes 100 percent increase for fringe benefits and overhead costs (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for each person to review this entire final rule. For each person that reviews this final rule, the estimated cost is therefore $900 (8 hours × $114.24). Therefore, we estimate that the maximum total cost of reviewing this entire final rule is $.7 million ($900 × 1,500 entities × 2 reviewers/entity).

We note that this analysis assumed two readers per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we expect it is more reasonable to estimate review time based on the number of contracting organizations because a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

C. Regulatory Flexibility Act (RFA)

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA). If a final rule may have a significant economic impact on a substantial number of small entities, then the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be 3 to 5 percent or more of the affected entities' costs or revenues.

For purposes of the RFA, we estimate that many affected payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used to classify businesses by industry and is used by the United States, Canada, and Mexico. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category.[98] Note that the most recent update to the NAICS classifications went into effect for the 2017 reference year. The latest size standards are for 2019.

As can be seen from the Summary of Annual Information Collection Requirements and Burden table (Table 12) in section IV.C. of this final rule, as well as Table 21 of this section, on average, the net cost to each plan to implement all provisions is significantly below $10,000 (the annualized cost over 10 years of $3.6 million divided by the number of contracts, about 1,000, is significantly below $10,000). Additionally, not all provisions apply to all plans. We do not believe this to be excessive burden even to small entities. Nevertheless, a more complete analysis is provided immediately below supporting the position that burden is not excessive.

Although States are also affected by these provisions, States are not classified as small entities and in any event the burden as just indicated is small.

The relevant NAICS category is Direct Health and Medical Insurance Carriers, NAICS 524114, with a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500

[98] North American Industry Classification System (2017). Retrieved from: *https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf. https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019.pdf.*

employees meeting the definition of small business.

MA organizations and Medicaid managed care plans have their costs funded by the Federal Government or State and therefore there is no significant burden. We discuss the details of this in this section. This discussion will establish that there is no significant burden to a significant number of entities from this final rule for these provisions.

1. Medicare Advantage

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay a basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified below). Payments to MA plans of the bid (or benchmark) amounts are risk adjusted and are higher for enrollees with risk scores above 1.0 and lower for enrollees with risk scores below 1.0.

MA and MA–PD plans can also offer supplemental benefits, that is, benefits not covered under Original Medicare or under Part D. These supplemental benefits are paid for through enrollee premiums, extra Government payments, or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a ''beneficiary rebate.'' The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare or Part D) and/or lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the Government's risk adjusted payments to plans for the bid plus the rebate exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the supplemental coverage available in many MA plans.

Part D plans, including MA–PD plans, submit bids and those amounts are paid to plans through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive government funds to cover most of premium and cost-sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the Government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this final rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, MA plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to making risk adjusted payments to the plan of either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is two percent, this is not considered substantial for purposes of the RFA.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government. However, the government additionally pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) It would follow that if the provisions of this final rule cause the MA bid to increase and if the benchmark remains unchanged or increases by less than the bid does, the result would be a reduced rebate and, possibly fewer supplemental benefits, or higher premiums for the health plans' enrollees. However as noted above, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit packages. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer more generous supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

2. Medicaid

We include Medicaid in this section since it is relevant to the proposed change to the applicable integrated plan definition at § 422.561. At § 422.561, we are expanding the universe of D–SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. Section 50311(b) of the BBA of 2018 amended section 1859(f)(8)(B) of the Act to direct establishment of procedures, to the extent feasible, unifying Medicare and Medicaid grievances and appeals. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs whose Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D–SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D–SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We believe that unified grievance and

appeals procedures are feasible for the additional D–SNPs and MCOs included in the revisions to the definition. While we are not imposing new Medicaid requirements, the applicable integrated plan definition change would expand the universe of Medicaid managed plans subject to the unified appeals and grievances provisions codified in the April 2019 final rule. However, the burden imposed by this final rule on Medicaid managed care plans is the one-time requirement to update their grievance and appeals procedures, which as estimated in Table 12, is a one-time cost of $7,582. Consequently, we have determined that this final rule will not have a significant impact on Medicaid managed care plans.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities. Based on the above, we conclude that the requirements of the RFA have been met by this final rule.

Comment: We received support, thanks, and encouragement from a large number of small business stakeholders including several organizations representing large numbers of small businesses. This support frequently echoed comments already made in the analysis: (i) The enormous expenses and rise of DIR, (ii) the lack of transparency resulting from pharmacy price concessions being collected a year or so after a small pharmacy had gained a profit and resulted in a net loss, (iii) the increased cost-sharing to enrollees, which can result in increased levels of medication non-compliance and lead to poorer health incomes. Commenters' criticism consisted of: (1) Requests for CMS to regulate the PBMs; (2) requests for extending the pharmacy price concessions provisions to the coverage gap; (3) requests for a delay of the effective date pointing to the burden of updating software and preparing for the 2023 bid; and (4) requests for further protections for small businesses and specialty pharmacies, which the commenters stated were very vulnerable and at risk for going out of business. Some commenters also noted that although this final rule is a step in the right direction, it does so on average and may not meet the needs of very small pharmacies not belonging to chains or pharmacies specializing in certain types of drugs.

Response: We thank the stakeholders for their support. With respect to the criticisms received: (1) We did not propose to impose any requirements directly on PBMs in the proposed rule. (2) After consideration of the comments, however, we modified our proposal to require pharmacy price concessions be applied to the negotiated price in the coverage gap. (3) We agree with the comment that pharmacies, including small pharmacies, need time to prepare software updates and that Part D sponsors will need time to prepare their 2023 bids. In response to comments here and as addressed previously, we are finalizing the proposal with a 2024 applicability date. We are also sympathetic to specialty pharmacies. CMS does not collect data on pharmacy price concessions at the pharmacy level, and this information is not publicly available. In order to estimate, for example, the effects on specialty pharmacies in particular, we would need to speculate on the relative difference between price concessions to those pharmacies versus retail pharmacies. As we do not have any basis for developing this difference, it is not possible to meaningfully analyze impacts by type of pharmacy.

We are therefore finalizing our analysis as presented above.

3. Rural Hospitals

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 fewer than 100 beds. This rule however is directed to plans and enrollees. Providers including hospitals receive the contracted rate or at least the original Medicare rate depending on whether the providers are contracted or not. Consequently, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Anticipated Effects

1. Enrollee Participation in Plan Governance (§ 422.107)

As described in section II.A.3. of this final rule, at § 422.107(f), we are finalizing our proposal that any MA organization offering a D–SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We are also finalizing at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D–SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. This final rule intends to ensure enrollees are engaged in defining, designing, participating in, and assessing their care systems. Section IV.B.1. of this final rule presents the collection of information burden for this provision.

To support D–SNPs in establishing enrollee advisory committees that meet the objective of this final rule in achieving high-quality, comprehensive, and coordinated care for dually eligible individuals, CMS would provide technical assistance to D–SNPs to share engagement strategies and other best practices. CMS can leverage the body of technical assistance developed for MMPs. For example, the CMS contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, to offer a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees.[99] CMS will be able to realize efficiencies by repurposing and building on these resources. Based on the existing technical assistance contracts held by CMS, we estimate an annual cost to the Federal Government of $15,000.

We received no comments on this proposal and therefore are finalizing this analysis without modification.

2. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§ 422.2)

We have presented a discussion of collection of information burden associated with this provision in section IV.B.3. of this final rule. In this section, we describe the impacts of our definition changes of: (1) Requiring exclusively aligned enrollment for FIDE SNPs; (2) capitation of Medicare cost-sharing; (3) clarifying the scope of services covered by a FIDE or HIDE; (4) Medicaid carve-outs; and (5) requiring service area overlap with the corresponding Medicaid plan. We anticipate all changes to the definition of FIDE SNP and HIDE SNP will result in additional time for CMS staff to review D–SNPs' contracts with State Medicaid agencies. We estimate that a GS level 13, step 5 (GS–13–5), employee will take an additional 20 minutes per State to confirm the contract meets the updated definitions. For CY 2022, 21 States have FIDE SNPs, HIDE SNPs, or both. Therefore, we estimate that the

[99] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/article/member-engagement/*.

final rule would result in 7 hours (20 minutes × 21 State contracts) of additional work for a GS–13–5 Federal employee. The 2021 hourly wage for a GS–13–5 Federal employee for the Baltimore Washington Area, which is close to the average hourly wage over all localities, is $56.31.[100] We allow 100 percent for fringe benefits and overtime, increasing the hourly wage to $112.62. Thus, the expected additional annual cost for reviewing the contract is $788.

a. Exclusively Aligned Enrollment for FIDE SNPs

As described in section II.A.5.a. of this final rule, we are requiring exclusively aligned enrollment for FIDE SNPs beginning in 2025. We noted that 12 D–SNPs may lose FIDE SNP status and no longer qualify for the frailty adjustment described in section 1853(a) of the Act and the regulation at § 422.308(c)(4). Of these 12 FIDE SNPs, six are currently receiving the frailty adjustment. We believe that these six FIDE SNPs are likely to have exclusively aligned enrollment by CY 2025 as only a small fraction of their current enrollment is currently unaligned and there are multiple options through which MA organizations can meet the requirement. Therefore, we do not believe the final rule will result in a significant reduction of Medicare payments from FIDE SNPs losing the frailty adjustment.

b. Capitation for Medicare Cost-Sharing and Behavioral Health Services for FIDE SNPs

We do not anticipate any cost transfers from the State to FIDE SNPs resulting from the final rule amendment of the definition of FIDE SNP (at § 422.2) to require that the capitated contract with the State Medicaid agency for a FIDE SNP must include coverage of Medicare cost-sharing (that is, payment by Medicaid of Medicare cost-sharing for the dually eligible individual), where applicable, and Medicaid behavioral health services. We initially estimated that all FIDE SNPs include coverage of Medicare cost-sharing in their capitated contracts with the State Medicaid agency; however, we learned that Tennessee does not capitate FIDE SNPs for cost-sharing. In this final rule, we are making the requirement related to cost-sharing applicable starting in 2025. We expect policy changes in Tennessee before 2025 will allow all current FIDE SNPs to meet the new definition. As noted in section II.A.5.b. of this final rule, most FIDE SNPs already include Medicaid behavioral health benefits in their capitated contracts with the State Medicaid agency. The remaining FIDE SNPs in California and Pennsylvania that do not currently cover Medicaid behavioral health benefits would likely become HIDE SNPs, which is also defined at § 422.2 (with revisions adopted in this final rule). These impacted D–SNPs would not experience a direct impact on costs when becoming a HIDE SNP as benefits covered by the impacted D–SNP would not change. Nor would impacted D–SNPs experience a change to Medicare revenue, as none of the impacted D–SNPs receive the frailty adjustment.

We received no comments on our analysis and are finalizing it without modification.

3. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this final rule, we are finalizing new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D–SNPs with exclusively aligned enrollment and how CMS would facilitate compliance with those contract terms. This final rule allows States to further promote integration using the State Medicaid agency contract with D–SNPs, with the goal of improving beneficiary experiences and health plan oversight. Section 422.107(e) applies only for State Medicaid agency contracts through which the State requires exclusively alignment enrollment, as defined in § 422.2, and establishes that States may choose to require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more State-specific D–SNPs and require that all such D–SNPs use integrated member materials.

a. State Medicaid Agency Contract Requirements

Section IV.B.4. of this final rule describes the total cost for the State to update the State Medicaid agency's contract with the D–SNPs in its market to address the changes in this final rule and consult with CMS to ensure contract changes meet the requirements at § 422.107(e). Half of the cost ($20,618) could be claimed by the State as Federal financial participation for administrative costs of the Medicaid program, born by the Federal Government. In addition to updating the State Medicaid agency contract, a State choosing to further integration through § 422.107(e) would need to determine readiness and make changes to State policy. The State's time and cost for adopting this final rule would depend on the State's current level of integration. For example, 11 States currently have a policy requiring some or all of the D–SNPs in the State to have exclusively aligned enrollment, and Massachusetts, New Jersey, and New York have worked with CMS to integrate some member materials. These States that have taken steps toward integration may use less time and resources to take advantage of the new processes at § 422.107(e) than States just beginning to integrate Medicare and Medicaid using D–SNPs. Given the uncertainty involved in estimating State behavior and levels of existing integration, we are not estimating any additional burden outside of updating the State Medicaid agency contract with D–SNPs. We did not receive any comments on what State resources would be needed to use the pathway for requiring or achieving higher integration and collaboration with CMS as described in § 422.107(e) in a State with limited D–SNP integration (for example, a State with no FIDE SNPs or HIDE SNPs).

b. Limiting Certain MA Contracts to D–SNPs

At § 422.107(e), we are codifying a pathway that would result, in certain circumstances, in contracts that only include one or more D–SNPs with exclusively aligned enrollment within a State. Because Star Ratings are reported at the contract level, having a contract with only the D–SNPs in a particular State would allow dually eligible individuals in that State to ascertain the full quality performance of a D–SNP and better equip States to work with their D–SNPs to improve health equity.

We describe the collection of information burden for MA organizations resulting from establishing a D–SNP-only contract in section IV.B.4.b. of this final rule. However, the additional Part C and D applications necessary to create separate contracts covering only D–SNPs in a particular state also result in additional Federal costs. While the collection of information packages lay out the Federal burden to process Part C and D applications, they do not list out the cost per contract application. We estimate the additional contract submissions for D–SNP only contracts would at most cost an additional $50,000 in labor burden for the Federal Government annually.

[100] See the locality pay tables for 2021 at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/*.

We note impacted D–SNP contracts may have changes to their quality bonus payments (QBP), as the new contract's payment will initially be calculated from the parent organization's enrollment-weighted average quality rating and eventually only on the performance under the new contract. We are unable to predict if QBPs will increase or decrease for these MA organizations due to separating D–SNPs from the original contracts into separate contracts.

c. Integrated Member Materials

As described in section II.A.6.b. of this final rule, to provide a more coordinated beneficiary experience we are finalizing at § 422.107(e) a pathway by which States and CMS would collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Section 422.107(e)(1) establishes factual circumstances that commit CMS to certain actions under paragraphs (e)(2) and (3).

In section IV.B.4.c. of this final rule, we note that we do not intend to significantly change timelines for D–SNPs to prepare materials, nor do we intend to mandate that States require D–SNPs to use integrated materials. We do not estimate any additional costs for States or plans to implement integrated member materials at § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. This final rule assures interested States that, under the conditions outlined in § 422.107(e), CMS would do its part to make it possible for D–SNPs to comply with State Medicaid agency contract terms for D–SNP-only contracts and integrated enrollee materials. Therefore, we do not estimate any additional burden for States or plans to implement integrated member materials at § 422.107(e).

We anticipate costs to CMS will be similar to past work done to collaborate with States to improve the integration and effectiveness of materials for dually eligible beneficiaries. To test materials, we conducted individual interviews with dually eligible individuals and desk reviews by contractors, CMS subject matter experts, and advocacy organizations. Since 2015, we have tested an integrated EOC, ANOC, SB, Formulary, and combined Provider and Pharmacy Directory.

We estimate that each of the model documents under § 422.107(e)—the SB, Formulary, and combined Provider and Pharmacy Directory—will require 40 hours of work from CMS staff (a GS–13–5 Federal employee) working at $112.62/hr. The projected cost to the Federal Government for 120 hours (40 hours × 3 documents) of a GS–13–5 employee is $13,500.

In our experience, a desk review from a contractor is approximately $10,000 per document and a study of the documents consisting of dually eligible individuals' interviews costs $25,000 per document. Therefore, we anticipate the contractor costs for integrated member materials to be $105,000 ($10,000 × 3 documents + $25,000 × 3 documents). Therefore, the total cost to the Federal Government of our final rule on integrating member materials is $118,500.

d. Joint State/CMS Oversight

In section II.A.6.c. of this final rule, we discuss our changes at § 422.107(e)(3) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at paragraph (e)(1). These coordination mechanisms include sharing relevant plan information, coordinating program audits, and consulting on network exception requests. We cannot estimate the cost of uncoordinated State and Federal oversight, but we believe this provision would result in a reduction in administrative burden for D–SNPs. States will have the ability to determine what level of resources is needed for their related work, and we believe States likely to elect to use the pathway described in § 422.107(e) would already have resources invested in coordinating care between MCOs and D–SNPs and would otherwise make choices that avoid significant increases in State burden.

At paragraph (e)(3)(i), we are finalizing that CMS would grant State access to HPMS, or any successor system, to facilitate monitoring and oversight for a D–SNP with exclusively aligned enrollment in an MA contract that only includes one or more D–SNPs operating within the State. Our final rule will require the State officials and employees accessing HPMS to comply with applicable laws and CMS policies and standards for access to that system, including keeping information confidential and maintaining system security. This access will allow State users the ability to directly view D–SNP information without requiring or asking the D–SNP to send the information to the States and would facilitate State-CMS communication on D–SNP performance since more people are able to review the data and information. MA organizations may benefit when it reduces the need for States to separately obtain the same information that is already available in HPMS.

Providing this HPMS access to State users would require HPMS contractors to update several modules, including user access and coding changes needed to implement the necessary access. HPMS contractors estimated that there would be a one-time update costing approximately $750,000.

We received no comments on our analysis and are finalizing it without modification.

4. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this final rule, we are finalizing a revision to which costs are tracked and accumulate toward the MOOP limit for dually eligible enrollees in MA plans under § 422.101(d) for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. Our rule will result in MA organizations that, under current policy, rarely or never pay cost-sharing above the MOOP limit for dually eligible enrollees being held responsible for payment of cost-sharing amounts above the MOOP limit. As a result, our final rule may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded to non-dually eligible individuals. However, in the short term, as we note above, MA organizations may prefer to reduce their profit margins, rather than raise their bids and thereby reduce the rebate dollars available for supplemental benefits.

Specifically, we are finalizing that all cost-sharing for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid (such as because of limits on Medicaid liability for Medicare cost-sharing under the lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals), is counted towards the MOOP limit. This will ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan must pay 100 percent of the cost

of covered Medicare Part A and Part B services. As a result, the State Medicaid agency will no longer be responsible for any Medicare cost-sharing for the remainder of the year. In addition, providers serving dually eligible MA enrollees with Medicare cost-sharing above the MOOP limit will be fully reimbursed for this cost-sharing for the remainder of the year. Now, some of that cost-sharing is unpaid because of limits on State payment of Medicare cost-sharing and prohibitions on collection of Medicare cost-sharing from certain dually eligible beneficiaries. We believe this change to the cost-sharing that MA organizations must use to determine when the MOOP limit has been reached will mitigate existing provider payment disincentives related to serving dually eligible MA enrollees. This change will also eliminate the perceived need for providers to bill dually eligible for non-paid coinsurance, which although prohibited, is not uncommon. As a result, this final rule may improve access to providers, including specialists, who currently limit the number of dually eligible MA enrollees they serve or decline to contract with D–SNPs. However, we are unable to quantify the extent to which any improved access would affect utilization of services by dually eligible MA enrollees and thereby affect Medicare spending.

Our final rule will increase the amount of MA organization payments to providers serving dually eligible individuals enrolled in MA plans after the MOOP limit is reached. As a result, our final rule may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded non-dually eligible individuals.

To estimate the costs of the final rule, we started with CY 2022 bid data to estimate the Medicare cost-sharing accrued by dually eligible beneficiaries with cost-sharing protections (full-benefit dually eligible individuals and QMB enrollees) above the mandatory MOOP level ($7,550 in 2022). We estimated the cost of Medicare cost-sharing above this MOOP level to be on average $22.99 per person per month. Then we multiplied this amount by 41 percent to reflect the portion of dually eligible enrollees in MA organizations that already accrue cost-sharing towards the MOOP level to arrive at $9.43 as the additional per person per month bid cost. Based on projected MA enrollment of dually eligible beneficiaries and other factors described in this section, this final rule would result in additional payments from MA organizations to health care providers serving high cost dually eligible MA enrollees, represented in the annual MA bid costs shown in column 2 of Table 13.

Only a portion of the projected higher MA organization bids for MOOP benefits represent higher costs to Medicare. MA rebates are calculated as an average of 68 percent of the difference between the bids and benchmarks. The additional cost to the Medicare Trust Funds is estimated to be the remaining 32 percent increase in bids. After reflecting the change in rebates, the per member per month cost to Medicare of the final rule is 32 percent of $9.43, or $3.

To project annual costs, we used projected enrollment by dually eligible beneficiaries in MA plans, as well as Trustee's Report U.S. Per Capita Costs (USPCC) cost and utilization trends. We also projected annual increases in the mandatory MOOP amounts under current regulations. The cost to Medicare based on our final rule will be partly offset by the savings to Medicaid for payment of Medicare cost-sharing over the MOOP limit for dually eligible individuals. While some State Medicaid agencies may save as much as the projected increase in bid costs per dually eligible MA enrollee in their State, the savings from this final rule will likely be less for most States. The majority of States have a ''lesser-of'' policy, under which the State caps its payment of Medicare cost-sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. We estimate that, based on average differences in State Medicaid and Medicare provider contracted rates, 39 percent of the costs of MOOP coverage under our final rule represents Medicaid savings. Of those savings, 57 percent accrue to the Federal Government based on the average FMAP rate of 57 percent. Those annual savings are shown in column 4 of Table 13.

Finally, 25 percent of the additional Medicare costs that represent Part B costs (Part B accounts for 60 percent of the costs of Parts A and B benefits provided by Medicare Advantage organizations) are offset by beneficiary premiums for Part B, as shown in column 6 of Table 13. The total Federal costs of the final rule, net of Federal Medicaid savings and the Part B premium offset are shown in column 7 of Table 13.

We note that there is uncertainty inherent in this analysis. In using the bid data, we made some assumptions about the extent to which MA organizations are already counting all cost-sharing in the plan benefit, including amounts paid by Medicaid programs, towards the MOOP limit. In addition, MA organizations may prefer to reduce their gain/loss margins, rather than substantially change their benefit package, when rebates are reduced in the short term. However, our estimate of the added bid benefit costs does not assume that MA organizations will absorb any portion of these costs by reducing their gain/loss margins.

TABLE 13: 10-YEAR AGGREGATE PROJECTED COSTS ($ MILLIONS) FROM MOOP PROVISION*

Year	Additional Bid Benefit Costs for MA Organizations for Cost-Sharing Above the MOOP	Total Medicare-Only Benefit Costs	Federal Savings to Medicaid from MOOP Provision	Medicare Costs minus Medicaid Savings	Part B Premium Offsets	Impact of MOOP Provision
(1)	(2)	(3) = 32% * (2)	(4) =39% * 57% * (2)	(5) = (3) - (4)	(6) = 60% * 25% *(3)	(7) = (5) - (6)
2023	805.8	257.9	179.1	78.7	38.7	40.0
2024	879.5	281.4	195.5	85.9	42.2	43.7
2025	963.2	308.2	214.1	94.1	46.2	47.9
2026	1,052.5	336.8	234.0	102.8	50.5	52.3
2027	1,145.8	366.7	254.7	111.9	55.0	56.9
2028	1,279.2	409.3	284.4	125.0	61.4	63.6
2029	1,391.1	445.2	309.2	135.9	66.8	69.1
2030	1,502.2	480.7	333.9	146.8	72.1	74.7
2031	1,619.7	518.3	360.1	158.2	77.7	80.5
2032	1,730.6	553.8	384.7	169.1	83.1	86.0
Totals	12,369.5	3,958.2	2,749.7	1,208.5	593.7	614.8

*Explanatory equations in the second row of the table are further elaborated on in the narrative.

No additional goods or services are being created. Rather, the money that States would pay or that would remain unpaid for Parts A and B services is now being paid by the plans and hence by the Trust Fund. Hence these amounts are considered transfers from the Trust Fund to the States.

We received no comments on our analysis and are finalizing this analysis without modification.

5. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

We are not scoring the finalized revisions to § 422.100(m) (Special Requirements during a Disaster or Emergency). As stated in the February 12, 2015 final rule (80 FR 7953), we recognize that disasters can create unavoidable disruptions and increased costs for MA organizations. Our primary goal during a disaster is the provision of continued and uninterrupted access to medically necessary plan-covered services for all enrollees. Our intention is to facilitate achievement of this goal by ensuring that plans facilitate increased access to providers from whom enrollees in the disaster area may seek high quality services at in-network cost-sharing. We do not believe that these temporary and unusual episodes of increased access will incentivize enrollees in a negative way or result in significant cost increases for affected MA organizations. We believe this is still relevant as most of our final revisions clarify our current policy. More detailed arguments for not scoring are presented after a discussion of the finalized revisions.

Our final amendments to § 422.100(m) include codifying our current practice of imposing the special requirements at § 422.100(m)(1) on MA organizations only when there is a disruption of access to health care as stated in the preamble to the February 12, 2015, final rule (80 FR 7953) and in our responses to comments and questions from MA organizations and others in administration of the existing requirement during the pandemic. We receive many questions and inquiries during a disaster or emergency so we believe this has been fully complied with; because we are clarifying through notice and comment rulemaking, these clarifications may result in enhanced compliance with this requirement and may contribute to reduced costs. Consequently, we do not believe the proposal to clarify what amounts to a disruption of access to health care and how the special requirements only apply when there is a disruption in connection with a declared emergency or disaster has an impact because it is consistent with current application of the regulation and MA organizations are already complying.

We are also finalizing adding a transition period of 30 days between a disaster or emergency ending and the end of the special requirements to § 422.100(m)(3). We do not believe these provisions would create impact. Some MA organizations may already allow flexibilities to enrollees following a disaster or emergency, such as a transition period to allow additional time for enrollees to return to in-network providers. Additionally, many MA plans have experience with disasters or other changes in cost that arise annually. The nature of the business cycle shows that MA plans may experience losses due to short-term disasters or emergencies in certain years, which may be offset with profits in the following years. Although the cost burden for a longer disaster or emergency is different than that for a shorter disaster, our recent experience with the COVID–19 PHE shows that CMS is aware of this cost burden and as each specific situation develops, is responding with certain flexibilities.

For these reasons, we are not further scoring the special requirements during a disaster or emergency provision.

6. Provisions Relating to Past Performance (§§ 422.504 and 423.505)

We are finalizing an update the past performance measures at 42 CFR 422.504 and 423.505 in order to better ensure CMS' capacity to limit new

applications and applications for service area expansions by low performers when these new plans and/or service area expansions would not be in the best interest of the Medicare program. Although there are no tangible costs to organizations, there may be future costs that may or may not occur. Organizations that fail to meet CMS' requirements will have applications denied, resulting in their inability to gain enrollment, thus losing potential future dollars. On the other hand, some organizations may actually improve performance, because of the ramifications of being a poor performer. In these cases, these organizations will actually be in a better position, potentially having higher Star Ratings, resulting in additional funds if the organization receives performance pay for their Star Ratings. The CMS costs are as follows:

- To perform the calculations, we estimate—

++ 2 staff at the GS 13–5 level working at $112.62/hr would have to perform a total of 24 hours of work (12 hours for each staff); and

++ 2 staff at the GS 14–9 level working at $148.74/hr would have to perform 10 hours of work.

- To notify plans, we estimate that 1 staff at the GS–13–5 level working at $112.62/hr will have to perform 3 hours of work.

The aggregate annual cost to the government is therefore $4,528.

7. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260, 423.2260, 422.2267, and 423.2267)

We have presented a discussion of collection of information burden associated with this provision in section IV.B.11. of this final rule. In this section, we summarize comments on the impacts of these provisions.

Comment: Comments suggested that the MLI as proposed would impose a greater burden on plans than we anticipated in the proposed rule. However, the comments suggesting this did not indicate why this was the case or what aspect of the burden we failed to address.

Response: On review, we believe our assessment of the burden on plans as discussed in the Regulatory Impact Assessment of this rule is accurate. We also believe the burden on plans is acceptable considering the vital nature of the MLI. As indicated earlier in the preamble and the response to a previous comment, certain required documents (under §§ 422.2267(e) and 423.2267(e)) are vital to a beneficiary's understanding of the MA, Part D, and cost plan programs. While those organizations must provide translation services, the requirement is less effective if beneficiaries are not aware of the availability of and right to the translation services. As such, the requirement to provide the MLI with required documents alerts the beneficiary to services that may help to prevent misunderstanding of the program and thus avoid beneficiary harm. Additionally, the MLI replaces OCR's analogous language assistance tagline requirement that was, based on scope and size, more burdensome than the MLI. Furthermore, CMS required plans to deliver the MLI until 2016, when it was replaced by OCR's analogous requirement. Finally, the MLI improves communication affecting a variety of health issues, acting as a bridge to education and awareness. This should ultimately improve beneficiary health and reduce the cost of beneficiary care.

8. Revisions to the Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

As discussed in section II.G. of this final rule, we are finalizing our proposal to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017, and to require separate reporting of amounts spent on supplemental benefits.

The paperwork burden associated with these provisions, $2.3 million, is estimated in section IV.B.12. of this final rule and included in the summary table below. There is also additional anticipated impact to the Federal Government. Most of the impact will arise from projections of future increases or decreases in MLR remittances, which are amounts that were originally paid from CMS to MA organizations or Part D sponsors, which they have to return to CMS (although the remittances go to the Treasury General Fund and not the Medicare Trust Funds from which they originated).

In the proposed rule, we explained that if we reinstate and add to the detailed MLR reporting requirements, as we proposed and are now finalizing, we will continue to pay a contractor to perform desk reviews and analyses of the reported data in order to identify omissions or suspected inaccuracies and to communicate its findings to MA organizations and Part D sponsors in order to resolve potential compliance issues, at a level comparable to the amount we paid for similar services for the contract years for which MA organizations and Part D sponsors were previously required to submitted detailed MLR data (that is, contract years 2014 through 2017). As a starting point for our analysis of the estimated cost increase associated with the additional desk review and analysis services that we anticipate a contractor will perform for us starting with contract year 2023 MLR reporting, we noted that, in the Regulatory Impact Analysis for the April 2018 final rule which had previously eliminated the detailed MLR reporting requirements, we assumed that by significantly reducing the amount of MLR data that MA organizations and Part D sponsors would be required to report to CMS annually starting with CY 2018, we had also eliminated the need for CMS to continue paying a contractor approximately $390,000 each year in connection with desk reviews of the detailed MLR reports. However, the April 2018 final rule indicated that the entire amount we paid to our desk review contractor would no longer be necessary once we stopped collecting detailed MLR data on an annual basis. As noted in the proposed rule, this has not been our experience, and in the years since we scaled back the reporting requirements, we have continued to find value in having our contractor perform MLR-related administrative tasks. Prior to CY 2018, the funding for these administrative tasks was included in the $390,000 figure that the April 2018 final rule identified as representing payment for desk reviews only. These administrative tasks include sending reminders to MA organizations and Part D Sponsors to submit their MLR data and attestations by the applicable deadlines, following up with MA organizations and Part D sponsors about their questions regarding their MLR submissions, and triaging communications to CMS so that matters requiring additional input from us are brought to our attention timely. CMS currently pays the contractor approximately $230,000 per year to perform these services.

The proposed rule estimated that, if we finalized the detailed MLR reporting requirements as we had, and if we resume conducting desk reviews of the detailed MLR data, we will increase the amount that we pay our contractor for desk reviews and MLR-related administrative services so that the total payment amount will approximately equal to the total amount we paid to our contractor for those services prior to the elimination of the detailed MLR reporting requirements (that is, $390,000). In other words, we expect that we will need to pay our contractor an additional $160,000 per year to

perform MLR desk reviews of the detailed MLR data that CMS will be requiring MA organizations and Part D sponsors to submit to us on an annual basis, starting with CY 2023, under the requirements we are now finalizing.

In addition, CMS currently pays a contractor $300,000 each year for software development, data management, and technical support related to MLR reporting. The Regulatory Impact Analysis for the April 2018 final rule estimated that we would be able to reduce this amount by $100,000 because we would no longer need to maintain and update the MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. However, contrary to our expectations, since CY 2018, CMS has continued to require technical support related to submission of the MLR Data Forms, such that, even without requiring significant updates to the MLR reporting software, we have continued to pay a contractor $300,000 for data management and technical support services. The proposed rule noted that we anticipate that we will continue to pay this amount for software development, data management, and technical support related to MLR reporting if the proposed changes to the MLR reporting requirements are finalized.

Table 14 presents expected additional payments (transfers) from MA organizations and Part D sponsors to the Treasury arising because they are projected to pay more in MLR remittances to the Treasury. These additional payments are transfers since no goods or services are being created. The impact to the Medicare Trust Funds is $0.

Based on internal CMS data, the raw average of total remittances for CYs 2014–2019 is $153 million. As discussed in section II.G.2. of this final rule, when CMS collected detailed MLR data pursuant to the reporting requirements that were in effect for CYs 2014–2017, the desk review contractor frequently detected potential errors or omissions in the reported data, which were brought to the attention of the MA organization or Part D sponsor that submitted the data, with a request to explain or correct the data. This process often resulted in the MA organization or Part D sponsor finding it necessary to resubmit the contract's MLR Report after revising the figures in the Report or attaching supplementary materials to explain details of its expense allocation methodology. A summary of the MLR remittances for the initial MLR submission versus the final MLR submission for CYs 2014–2017 can be found in Table 14. These 4 years represent the time period when detailed MLR data was submitted to CMS and subjected to desk reviews.

TABLE 14: CHANGE IN MLR REMITTANCES BETWEEN INITIAL AND FINAL MLR SUBMISSION

Contract Year (CY)	Initial MLR Submission	Final MLR Submission	Change	Percent Change
2014	36,884,719	37,074,217	189,498	0.5%
2015	28,128,535	22,064,688	(6,063,847)	-27.5%
2016	200,308,358	242,402,915	42,094,557	17.4%
2017	223,244,933	222,058,179	(1,186,754)	-0.5%
2014–2017	488,566,545	523,599,999	35,033,454	6.7%
2018	92,639,916	94,502,390	1,862,474	-----
2019	298,124,406	298,124,406	-----	-----
Average (2016–2019):[1]		204,045,022	-----	-----

[1]The average remittance is calculated using the initial MLR submission for CYs 2016 and 2017 and the final MLR submission for CYs 2018 and 2019.

The percent change in MLR remittances increased on average 6.7 percent between the initial and final MLR submissions during the MLR desk review periods for CYs 2014–2017. We anticipate that, if finalized, the amendments to §§ 422.2460 and 423.2460 would increase future remittance amounts by an average of 6.7 percent due to CMS receiving detailed MLR data and conducting desk reviews of the detailed MLR data.

To estimate the amount of additional remittances under the regulations we are adopting in this final rule, we evaluated the MLR for those contracts that failed to meet the 85 percent minimum MLR requirement for CYs 2016–2019. The MLR remittances for CYs 2014 and 2015 were much lower than those for the more recent years and so these older years were excluded from the base period that is used to project future remittances. For CYs 2016 and 2017, we examined the MLR prior to desk reviews, or in the Initial MLR Submission. For CYs 2018 and 2019, when there were not desk reviews of detailed MLR data, we examined the finalized total MLR remittances. The average remittances for these years (CYs 2016 and 2017 prior to desk reviews and CYs 2018 and 2019) equaled $204.0 million. In order to project the increase in remittances for CYs 2023–2032, the $204.0 million was inflated using estimated enrollment and per capita increases based on Tables IV.C1. and IV.C3. of the 2021 Medicare Trustees Report, with ordinary inflation (Table II.D1. of the 2021 Medicare Trustees Report) carved out of the estimates. We continued to assume that remittance amounts would increase by 6.7 percent for the entire projection period due to the restatement of desk reviews of detailed MLR data, after the application of enrollment and per capita increases.

Table 15 is based on data from the Office of the Actuary, some of which may be found in the annual Trustees Report. The calculations started with a $13.7 million additional cost to MA organizations and Part D sponsors in CY

2019 (This amount is not shown in the table which is a 10 year table starting from CY 2023). The cost in each successive contract year is obtained by adding the MA enrollment increases expressed as a percentage in column (2), then adding the average annual per capita increase in expenditures, expressed as a percentage in column (3), and then dividing by ordinary inflation expressed as a percentage column (4). The calculations can be illustrated starting with the CY 2023 net cost ($20.3 million) and deriving the $21.5 million CY 2024 cost. We have $20.3 million * (1+3.8%) * (1+4.8%) / (1+2.5%) = $21.5 million.

TABLE 15: MLR COST (TRANSFERS) FROM MA ORGANIZATIONS AND PART D SPONSORS ($ MILLIONS) TO THE TREASURY

Contact Year	MA Enrollment Increase	Average Annual Per Capita Increase in Expenditures	Ordinary Inflation	Net Cost (Savings) ($ millions)
(1)	(2)	(3)	(4)	(5)
2023	4.1%	4.8%	2.5%	20.3
2024	3.8%	4.8%	2.5%	21.5
2025	3.7%	5.4%	2.5%	22.9
2026	3.6%	5.4%	2.5%	24.4
2027	3.3%	5.3%	2.5%	25.9
2028	3.1%	5.5%	2.5%	27.5
2029	2.8%	5.5%	2.5%	29.1
2030	2.6%	4.4%	2.5%	30.4
2031	2.3%	7.2%	2.4%	32.6
2032	1.8%	4.9%	2.4%	34.0
Totals				268.6

We are finalizing our impact analysis without change.

9. Pharmacy Price Concessions in the Part D Negotiated Price (§§ 423.100 and 423.2305)

As discussed in section II.H.3. of this final rule, at §§ 423.100 and 423.2305, we are finalizing our proposal to adopt a new definition of ''negotiated price'' to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug through all phases of the Part D benefit In response to comments, we will retain the current regulatory definition of ''negotiated prices'' for 2023 and delete the current definition of ''negotiated prices'' (in the plural) and add a definition of ''negotiated price'' (in the singular) to make clear that a negotiated price can be set for each covered Part D drug, and the amount of the pharmacy price concessions may differ on a drug by drug basis for 2024 and thereafter. We are finalizing the definition of ''negotiated price'' that was proposed and that is intended to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all pharmacy price concessions beginning with plan year 2024 onward. The requirement to apply pharmacy price concessions the negotiated price will apply in all phases of the Part D benefit.

The provision would have several impacts on prescription drug costs for government, beneficiaries, Part D sponsors, and manufacturers. Tables 16, 17, and 18 summarize these impacts, which are discussed in more detail in the narrative that follows. We note that this provision would also have one-time administrative costs for Part D sponsors. This cost is discussed in the Collection of Information section of this final rule.

a. Impact on Prescription Drug Costs for Government, Beneficiaries, Part D Sponsors, and Manufacturers

Tables 16, 17, and 18 summarize the 10-year impacts we have modeled for requiring that sponsors apply all pharmacy price concessions to the negotiated price in all phases of the Part D benefit. These tables estimate a modest potential indirect effect on pharmacy payment as a result of pharmacies' independent business decisions. Specifically, the estimates assume that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and we assume that these business decisions will result in a slight increase in pharmacy payments of 0.2 percent of Part D gross drug cost.

Tables 16, 17, and 18 reflect the impact of these provisions to enrollees, manufacturer gap discounts, and the Federal Government respectively. Overall beneficiaries are expected to save $26.5 billion, manufacturers pay $16.8 billion less in gap discounts, and the government cost is expected to increase $46.8 billion dollars over 2024–2032.

Under this provision, we anticipate that beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder for most drugs, beginning immediately in the year the proposed change would take effect (2024). (This is summarized in Table 16 in the row ''Beneficiary Costs'' which reflects a sum of the rows ''Cost-sharing'' and ''Premiums.'') Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low-income beneficiaries, and on average we expect these cost-sharing decreases would exceed the premium increases. While the amounts will vary

depending on an individual beneficiary's prescriptions, plan sponsor benefits, and contractual arrangements, we expect more than half of the non-low-income, non-employer group beneficiaries to see lower total costs, inclusive of cost-sharing decreases and premium increases. For example, a beneficiary who takes no medications will probably see a premium increase and no cost-sharing decreases, whereas a beneficiary who takes several medications each month is likely to see cost-sharing decreases that are greater than the premium increase. For low-income beneficiaries, whose out-of-pocket costs are funded through Medicare's low-income cost-sharing payments, cost-sharing savings resulting from lower point-of-sale prices would accrue to the Government. Plan premiums would likely increase as a result of the change to the definition of negotiated price—if pharmacy price concessions are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability in the bid, which would have the effect of increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations would be large enough to lower beneficiaries' overall out-of-pocket costs on average.

The increasing cost of coverage under Part D plans as a result of pharmacy price concessions being applied at the point of sale as proposed would likely have a more significant impact on Government costs, which would increase overall due to the significant growth in Medicare's direct funding of plan premiums and low-income premium payments. However, partially offsetting the increase in direct funding and low-income premium payment costs for the government would be decreases in Medicare's reinsurance and low-income cost-sharing payments. Decreases in Medicare's reinsurance payments result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the Government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low-income cost-sharing payments would decrease if beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing aggregate manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it. These effects are presented in Table 18.

These impacts assume that the definition of ''negotiated price'' would apply for Part D drugs in all phases of the Part D benefit (applicable drugs in the coverage gap phase of the benefit). While we initially proposed excluding the coverage gap phase from this policy, we are finalizing the alternative proposal which applies this policy to the entire benefit. This policy increases beneficiary savings and government costs relative to the initial proposal, but simplifies administration and provides greater transparency to beneficiaries.

Table 16 shows the increased total savings to enrollees which is projected to be $26.5 billion for the period from 2024–2032. As explained in the previous narratives, the total savings to enrollees' accounts for both cost-sharing savings and expected premium increases.

TABLE 16. TOTAL IMPACTS TO ENROLLEES (BILLIONS $) FOR 2024 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Beneficiary Costs	$0.00	$0.00	($1.73)	($1.88)	($2.04)	($2.39)	($2.77)	($3.20)	($3.65)	($4.15)	($4.69)	**($26.5)**	**($20.4)**
Cost-Sharing	$0.00	$0.00	($2.62)	($2.85)	($3.10)	($3.63)	($4.22)	($4.86)	($5.57)	($6.33)	($7.16)	**($40.3)**	**($31.8)**
Premium	$0.00	$0.00	$0.89	$0.97	$1.05	$1.24	$1.44	$1.67	$1.91	$2.18	$2.47	**$13.8**	**$11.4**

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of $

TABLE 17: TOTAL IMPACTS TO MANUFACTURERS (BILLIONS $) FOR 2024 THROUGH 2032 WITH APPLICATION IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Manufacturer Gap Discount	$0.00	$0.00	($1.25)	($1.37)	($1.51)	($1.66)	($1.83)	($2.00)	($2.19)	($2.38)	($2.59)	($16.8)	($13.8)

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

TABLE 18: TOTAL IMPACTS TO GOVERNMENT FOR 2024 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	TOTAL With Gap	Total Without Gap
Government Costs	$0.00	$0.00	$3.27	$3.56	$3.88	$4.41	$4.98	$5.60	$6.27	$7.00	$7.78	$46.8	$38.1
Direct Payments	$0.00	$0.00	$6.74	$7.29	$7.95	$8.83	$9.78	$10.80	$11.90	$13.07	$14.32	$90.7	$72.4
Reinsurance	$0.00	$0.00	($1.92)	($2.08)	($2.29)	($2.28)	($2.26)	($2.22)	($2.16)	($2.09)	($1.98)	($19.3)	($13.9)
LI Cost-Sharing	$0.00	$0.00	($1.83)	($1.96)	($2.12)	($2.53)	($2.98)	($3.48)	($4.02)	($4.62)	($5.27)	($28.8)	($23.8)
LI Premium	$0.00	$0.00	$0.29	$0.31	$0.33	$0.38	$0.44	$0.50	$0.56	$0.63	$0.71	$4.2	$3.4

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

We received comments on our impact analysis.

Comment: A commenter stated that while this final rule is a step in the right direction CMS must conduct a complete regulatory impact analysis of how this

rule affects all types of specialty pharmacies. There was concern that because of the more expensive drugs sold by specialty pharmacies that this final rule would not meet their needs even though in aggregate it improved the program.

Response: CMS does not collect data on pharmacy price concessions at the pharmacy level, and this information is not publicly available. In order to estimate, for example, the effects on specialty pharmacies in particular, we would need to speculate on the relative difference between price concessions to those pharmacies versus retail pharmacies. As we do not have any basis for developing this difference, it is not possible to meaningfully analyze impacts by type of pharmacy.

Comment: A commenter offered that in addition to the financial impacts described in the rule, there may be additional improvements in health outcomes and medical costs resulting from improved medication adherence as a result of lower negotiated prices.

Response: We agree that it is possible that there will be effects on health outcomes. We do not have adequate information to quantify these impacts at this time because the actual cost-sharing effects will vary considerably with how plan sponsors reflect this in their benefit design. For example, it is possible that the plans will concentrate these effects on certain categories of drugs, and many health effects may take several years to realize.

Comment: We received several comments requesting that the financial impacts include analysis by type of retail pharmacy.

Response: We do not have sufficient data to determine impacts by type of pharmacy, as the pharmacy price concessions are not reported in connection to a particular pharmacy or type of pharmacy.

Comment: A commenter stated that CMS did not disclose their assumptions in developing the tables. These would include future Part D membership, trends in drug utilization, drug cost, network contracting, manufacturer rebates, drug mix, benefit designs, and general inflation. The commenter noted that CMS did disclose that they assumed pharmacies would seek to retain 2 percent of the existing pharmacy concessions for risk and cashflow. Most importantly, CMS did not disclose how lowest reimbursement was applied in the model.

Response: We modeled the lowest reimbursement as the negotiated price, rather than having bonus payments to pharmacies that would lower DIR and therefore lead to higher premiums. Aggregate forecasts for the Part D program payments, including cost and DIR trends similar to those used in our analysis, may be found in the Medicare Trustees Report for 2021, a publicly available resource (*https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf*). More detailed assumptions are based on CMS internal data that is not public, and if made public could adversely affect Part D bid submissions, such as drug mix or beneficiary progression through the benefit. For example, sharing the assumptions on the projected mix of price concessions by drug could allow sponsors to infer whether their current mix presents opportunities for greater price concessions on certain drugs.

Comment: Several commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. The actuary performing the independent analysis believed that the CMS assumption of pharmacies negotiating 2 percent of the concessions would produce a different value than what was shown in the proposed rule.

Response: We assumed that 2 percent of only the existing pharmacy price concessions impacted by this policy are reflected as an offset to pharmacies for the change in cashflow and risk. As the proposed rule specified that the new definition for the term ''negotiated price'' would not apply in the coverage gap, we did not apply the 2 percent assumption to price concessions in the coverage gap in the proposed rule. This difference between applying the 2 percent assumption to the entire benefit or excluding the coverage gap explains the discrepancy.

As the proposed rule specified that the new definition for the term ''negotiated price'' would not apply in the coverage gap, we did not apply the 2 percent assumption to price concessions in the coverage gap in the proposed rule.

Comment: Several commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. The actuary performing the independent analysis noted that premium is an important factor—perhaps the most important factor—in the purchase decisions of members.

Response: We agree that Part D sponsors are highly motivated to keep premiums low. CMS agrees that premiums are a key factor influencing insurance purchasing decisions and we have taken premium levels into account in our analysis.

Comment: A commenter questioned the difference between the calculations provided in the Alternative Analysis section of the proposed rule (section V.E.2.) and the calculations provided in the narrative in section V.D.8. of the proposed rule, the difference between them being inclusion of the coverage gap. The commenter questioned the validity of assuming a 6% drop in manufacturer cost between the two tables.

Response: We thank the commenter for their feedback. The manufacturer cost is impacted not only directly by the change in negotiated price used for calculating the coverage gap discount on a particular drug, but also by changing the amount of spending in the gap phase of the benefit. As negotiated prices decrease from this policy, there is less spending in the coverage gap phase of the benefit.

Comment: A commenter provided an alternative analysis that considered the effects of an incentive payment of 4.3 percent of drug cost to the pharmacies after the point of sale, rather than the net payment to the pharmacy paid at the point of sale assumed in the RIA. They noted that this is another possible payment arrangement under the proposed rule.

Response: While an interesting example, we believe this approach is unlikely. A bonus payment to pharmacies would further increase premiums because it would decrease the DIR paid to the plan sponsor. Recent data indicate an increase in DIR of 512 percent between 2009 and 2018, which suggests plan sponsors are very focused on increasing DIR.

Comment: A few commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. These analyses assumed pharmacy DIR was applied at the POS in all phases including the coverage gap. The results were generally consistent with the direction and magnitude of CMS's overall findings by stakeholder. The independent analyses assumed no behavior changes among stakeholders, which, if considered, could have a material impact on the estimates. The independent analyses indicated that at best 29 percent of beneficiaries may see cost-sharing savings that exceed their increases in premiums. By contrast, at least 38 percent of beneficiaries may realize higher net costs, as their premium increases typically outweigh their cost-sharing savings, and 33 percent (low income enrollees) may see little or no change in OOP costs.

Response: We appreciate the feedback and additional analysis shared in this comment. As noted by the commenter, the overall magnitude and direction of

cost impacts is broadly similar to the results in the regulatory impact analysis. We agree that low income beneficiaries will not see significant impacts from the rule. We do not wholly agree with the percentages of beneficiaries described in the analysis. For non-low income beneficiaries, we disagree with the characterization in the comment that no beneficiaries ending in the deductible phase will benefit. On the contrary, those beneficiaries who are nearly at the end of the deductible could see substantial cost decreases as they are paying the full negotiated price of any drug in that phase. This is also implicitly acknowledged in the independent analysis with the caveat that beneficiaries in this phase would ''typically'' not see a cost decrease.

We are finalizing our impact analysis without change. We appreciated the additional analysis provided by commenters. For the more complete analysis providing a range of potential future impacts, we note that our estimates of government cost are within the range they estimated. We believe the independent analysis largely confirms our results and the majority of differences are due to more granular data in the CMS analysis.

E. Alternatives Considered Analysis

The major drivers of cost and transfers in this rule include the MLR and Part D pharmacy price concessions provisions. The aggregate impact of each of these over 10 years exceeds $100 million. Alternative analysis is provided below for these provisions.

1. Alternatives Related to the Medical Loss Ratio Reporting Requirements (42 CFR 422.2460, 423.2460)

As an alternative to our proposal to reinstate and add to the detailed MLR reporting requirements in effect for CYs 2014–2017, we considered continuing to collect minimal MLR data, as required under current §§ 422.2460 and 423.2460, and to use our authority under §§ 422.2480 and 423.2480 to require that entities selected for MLR audits provide us with more detailed MLR data, and with any underlying records that can be used to substantiate amounts included in the calculation of each contract's MLR and the amount of any remittance owed to CMS. In addition to their primary function as a mechanism for obtaining information that can be used to validate audited MA organizations' and Part D sponsors' compliance with the applicable requirements for calculating and reporting MLR information to CMS, we believe that audits are in general well-suited for examining matters such as where and how calculation errors occur, and identifying areas where we might be able to reduce the incidence of errors through revisions to our regulations and guidance. By contrast, desk reviews of detailed MLR data are more useful for quickly reviewing large amounts of data in order to identify possible errors or omissions that might affect the MLR calculation, and for identifying market-wide trends in how MA organizations and Part D sponsors might be adjusting their expenditures in response to rule or policy changes that affect how MLRs are calculated. Given CMS' interest in better understanding how MA organizations and Part D sponsors' are calculating their MLRs in general, and in flagging areas where calculation errors might be impacting the MLR calculation so that they can be addressed promptly, we decided that our goals would be better served if we were to require MA organizations and Part D sponsors to report detailed MLR data to us directly, and to subject that data to desk reviews, rather than to attempt to collect the same or similar MLR data using our audit authority.

An additional reason we chose at this time not to rely solely on MLR audits to identify errors in MA organizations' and Part D sponsors' MLR submissions is that we believe this approach would result in a greater burden for the Federal Government and cumulatively across all MA organizations and Part D sponsors than would the proposed reinstatement of the detailed MLR reporting requirements. We note that, in the April 2018 final rule, CMS indicated that we did not believe that eliminating the detailed MLR reporting requirements would weaken MLR compliance oversight, and in connection with this we noted that had not changed our authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 for purposes of determining that remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c) and (d) and 423.2410(c) and (d) were accurately calculated, reported, and applied (73 FR 16675). However, in that rule, we did not account for the increased cost to CMS, or the additional cumulative burden across all MA organization and Part D sponsors, if we were to scale up our MLR audit operations to a sufficient degree to perform effective compliance oversight in the absence of detailed MLR reporting requirements.

Based on CMS' historical costs in auditing MLRs, we estimate that individual audits would cost the government approximately $71,000 per audit. We anticipate that, in order to effectively monitor MLR compliance using audits, we would need to audit one-third of MA and Part D contracts, or an average of 194 contracts per year, at a cost of approximately $13.8 million per year. By contrast, we estimate that the proposed reinstatement of the detailed MLR reporting requirements would result in a relatively small increase in burden for MA organizations and Part D sponsors, as we expect that they would already need to be tracking most of the information included in the detailed MLR Report template in order to calculate their MLRs in accordance with current requirements.

2. Alternatives Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

As discussed in section II.H.3. of this final rule, we proposed to adopt a new definition of ''negotiated price'' to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug.

In the analysis provided in section IV.D.8. of this final rule, we estimate the impact of our proposal to require application of pharmacy price concessions to the negotiated price at the point-of-sale in all phases of the Part D benefit. In this alternative analysis, we consider the added impact of only requiring application of pharmacy price concessions to the negotiated price of applicable drugs outside of the coverage gap phase.

This alternative proposal would be more complex, but produces a smaller premium impact. Given that Part D sponsors are highly focused on premium targets for their competitive position, we would expect the pharmacy price concessions to be held back from the point of sale transaction and reimbursed at a later date.

Table 19 shows decreased savings to pharmaceutical manufacturers if pharmacy price concessions are applied to applicable drugs in the coverage gap.

Table 20 shows the impact to the Government. As explained in the narrative of section IV.D.8. of this final rule, the total Government cost reflects four separate components including direct payments, reinsurance, low

TABLE 19*: IMPACT ($ BILLIONS) OF CONCESSIONS EXCLUDES APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP AND USES A 2023 STARTING DATE

TA

Label	Item/Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
(A)	Gross Drug Covered Cost (GDCC)	-$14.4	-$15.8	-$17.2	-$19.0	-$20.9	-$22.9	-$25.0	-$27.3	-$29.8	-$32.4
(B)	Drug Cost Covered by Plan (Supplemental and non-Part D) CCP	-$10.5	-$11.6	-$12.7	-$13.6	-$14.6	-$15.6	-$16.7	-$17.9	-$19.1	-$20.3
(C)	OOP including Gap Discount	-$3.9	-$4.2	-$4.6	-$5.4	-$6.3	-$7.2	-$8.3	-$9.4	-$10.7	-$12.1
(D)	General Premium Payment	$4.8	$5.2	$5.6	$6.3	$7.0	$7.8	$8.6	$9.5	$10.4	$11.4
(E)	Reinsurance	-$1.4	-$1.6	-$1.7	-$1.7	-$1.7	-$1.7	-$1.6	-$1.6	-$1.5	-$1.4
(F)	LIS Cost-Sharing	-$1.2	-$1.3	-$1.4	-$1.7	-$2.1	-$2.4	-$2.8	-$3.3	-$3.8	-$4.3
(G)	LIS Premium	$0.2	$0.2	$0.2	$0.3	$0.3	$0.4	$0.4	$0.5	$0.5	$0.6
(H)	Total Government	**$2.3**	**$2.5**	**$2.7**	**$3.1**	**$3.6**	**$4.0**	**$4.5**	**$5.1**	**$5.7**	**$6.3**
(I)	Enrollee Cost-Sharing	-$1.7	-$1.9	-$2.0	-$2.4	-$2.8	-$3.3	-$3.8	-$4.4	-$5.0	-$5.7
(J)	Enrollee Premiums	$0.6	$0.7	$0.7	$0.9	$1.0	$1.2	$1.4	$1.6	$1.8	$2.0
(K)	Total Enrollee Costs	-$1.1	-$1.2	-$1.3	-$1.5	-$1.8	-$2.1	-$2.5	-$2.8	-$3.2	-$3.6
(L)	Total Benefits	2.9	3.2	3.5	4.0	4.6	5.2	5.9	6.7	7.5	8.4
(M)	Gap Discount	-$0.9	-$1.0	-$1.1	-$1.2	-$1.4	-$1.5	-$1.6	-$1.8	-$1.9	-$2.1

*Negative numbers indicate savings. Positive numbers indicate costs. Row totals are found in Table 17.

income cost-sharing payments, and low-income premium payments. We note, that this cost is a transfer. More specifically, the identical Rx that was formerly paid for by enrollees is now being paid for by the Government.

TABLE 20*: TOTAL IMPACTS FOR 2023 THROUGH 2032 WITHOUT APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

	Total (in $ billions)	Per Member-Per-Year 2023–2032[1]	Percent Change
Beneficiary Costs (K)	($21.30)	($36.66)	-2%
Cost-Sharing (I)	($33.10)	($57.03)	-6%
Premium (J)	$11.80	$20.37	5%
Government Costs	$40.00	$69.17	3%
Direct Payment (D)	$76.70	$132.47	83%
Reinsurance (E)	($15.80)	($27.27)	-2%
LI Cost-Sharing (F)	($24.40)	($42.15)	-5%
LI Premium (G)	$3.50	$6.13	7%
Manufacturer Gap Discount (M)	($14.60)	($25.19)	-6%

*Negative numbers indicate savings; positive numbers equal costs. Minor discrepancies between the sums in Tables 16 and 17 are due to rounding.

Note: These values represent the annualized average impacts divided by the average total Part D projected enrollees. Actual impacts will vary depending on beneficiary status and plan.

F. Accounting Statement and Table

In accordance with OMB Circular A–4, Table 21 depicts an accounting statement summarizing the assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 21: ACCOUNTING STATEMENT

Category	Estimate at 7% (In 2022 Dollars)	Estimate at 3% (In 2022 Dollars)	Years Covered	Affected Stakeholders
Net Annualized Monetized Cost ($ Millions)	3.1	3.1	CYs 2023-2032	MA organizations, Part D sponsors, and contractors for the Federal Government
Net transfers from the Medicare Trust Fund ($ Millions)	4,341.7	4,564.1	CYs 2023-2032	The transfers in this row combine: (1) transfers arising from the pharmacy price concessions provision from the Medicare Trust Fund to plan enrollees and pharmaceutical manufacturers; and (2) transfers arising from the MOOP provision from the Medicare Trust Fund to States and providers of duals.
Transfers to the United States Treasury ($ Millions)	26.0	26.5	CYs 2023-2032	The transfers in this row arising from the MLR provision are from MA organizations and Part D sponsors to the United States Treasury.

Table 21 is based on the summary of costs presented in Tables 22 and 23. Tables 22 and 23 reflect all costs in both the COI and RIA sections. This summary table allocates impact by year and by whether it is a cost or transfer (no provisions of this rule have a savings impact). In all tables, costs are expressed as positive amounts.

However, in the transfer row negative numbers correspond to payments by the government (which in the provisions of this rule may come from the Treasury or Medicare Trust Fund) while positive

numbers indicate savings. There are 3 transfers in this rule: The MOOP provision is a cost to the Medicare Trust Fund (TF) (the corresponding gain to States and providers of duals in equal amounts is not shown in Tables 22 and 23). The MLR provision is a savings to the Treasury (the corresponding loss in equal amount to the plans is not shown in the Tables 22 and 23). The pharmacy price concessions provision incurs a cost to the Medicare Trust Fund, and savings to enrollees and manufacturers. However, there is a small difference between what the Trust Fund pays and what beneficiaries and manufacturers gain. The difference is due to the assumption that pharmacies will seek to retain a small portion of the current DIR to compensate for differences in cash flow and pricing risk. Therefore, Tables 22 and 23 list separately the impacts on the Trust Fund, the enrollees, and the manufacturers. However, the row ''Total transfers from the Trust Fund'' only reflects the sum of the Trust Fund payments for the pharmacy price concessions provision and the MOOP provision (it does not offset this amount by the savings to enrollees and manufacturers). Similarly, Table 21 reflects separately, annualized transfers to the Treasury and annualized transfers from the Trust Fund for the MOOP and pharmacy price concessions provision. Thus, complete detailed amounts on all provisions may be found in Tables 22 and 23.

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TABLE 22: SUMMARY TABLE OF COSTS and TRANSFERS BY PROVISION AND YEAR ($ MILLIONS)

	2023 Costs	2023 Transfers	2024 Cost	2024 Transfers	2025 Cost	2025 Transfers	2026 Cost	2026 Transfers	2027 Cost	2027 Transfers
Total Costs	2.8		4.2		3.9		2.8		2.8	
Total transfers (United States Treasury)		20.3		21.5		22.9		24.4		25.9
Total Transfers (Medicare Trust Fund)		(40.0)		(3312.0)		(3604.2)		(3933.1)		(4464.2)
MOOP		(40.0)		(43.7)		(47.9)		(52.3)		(56.9)
Enrollee Advisory Committee					1.0		1.0		1.0	-
HRAs			0.0							
Network Adequacy	0.0		0.0		0.0		0.0		0.0	
HIDE, FIDE Definition					0.0					
D-SNP contracts					1.1					
Past Performance					0.0					
Unified Appeals/Grievances	0.0									
Marketing Multi-language insert	0.3		0.3		0.3		0.3		0.3	
MLR Paperwork	2.3		2.3		2.3		2.3		2.3	
MLR Treasury		20.3		21.5		22.9		24.4		25.9
MLR Contractor	0.2		0.2		0.2		0.2		0.2	
Rx PDE Transmission Costs			1.4		0.1		0.1		0.1	
Rx cost to TF (expressed as a negative number)				(3268.3)		(3556.3)		(3880.8)		(4407.2)
Rx Savings Enrollees				1731.1		1882.9		2044.0		2393.0
Rx Savings Manufacturers				1251.6		1368.2		1512.6		1664.3

NOTE: Entries of $0.0 reflect rounding to tenths of a million. However, the sum of these numbers adds a total of about $0.1 million and hence these numbers were included. The numbers are obtained by dividing the corresponding numbers in the Summary COI table by 1,000,000. Positive numbers in the cost columns represent costs. In the transfer columns, positive numbers indicate savings to the Federal Government while negative numbers indicate costs to the Federal Government.

TABLE 23: SUMMARY TABLE OF COSTS AND TRANSFERS BY PROVISION AND YEAR ($ MILLIONS)

	2028 Costs	2028 Transfers	2029 Cost	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	Raw 10 Year Totals
Total Costs	2.8		2.8		2.8		2.8		2.8		30.6
Total transfers (United States Treasury)		27.5		29.1		30.4		32.6		34	268.6
Total Transfers (Medicare Trust Fund)		(5041.7)		(5670.6)		(6348.9)		(7082.2)		(7869.6)	(47366.6)
MOOP		(63.6)		(69.1)		(74.7)		(80.5)		(86.0)	(614.8)
Enrollee Advisory Committee	1		1		1		1		1		7.7
HRA											0.0
Network Adequacy	0.0		0.0		0.0		0.0		0.0		0.0
HIDE, FIDE Definition											
D-SNP contracts											1.1
Past Performance											
Unified Appeals/Grievances											
Marketing Multi-language insert	0.3		0.3		0.3		0.3		0.3		3.1
MLR Paperwork	2.3		2.3		2.3		2.3		2.3		22.9
MLR Treasury		27.5		29.1		30.4		32.6		34	268.6
MLR Contractor	0.2		0.2		0.2		0.2		0.2		1.6
Rx Admin	0.1		0.1		0.1		0.1		0.1		1.9
Rx cost to TF (expressed as a negative number)		(4978.1)		(5601.4)		(6274.2)		(7001.7)		(7783.6)	(46751.8)
Rx Savings Enrollees		2775.0		3195.0		3652.0		4150.3		4690.3	26513.5
Rx Savings Manufacturers		1826.1		2000.6		2185.9		2382.4		2588.9	16780.7

NOTE: Entries of $0.0 reflect rounding to tenths of a million. However, the sum of these numbers adds a total of about $0.1 million and hence these numbers were included. The numbers are obtained by dividing the corresponding numbers in the Summary COI table by 1,000,000. Positive numbers in the cost columns represent costs. In the transfer columns, positive numbers indicate savings to the Federal Government while negative numbers indicate costs to the Federal Government.

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F. Conclusion

The previous analysis, together with the preceding preamble, provides an RIA. This rule at an annualized average cost of 3.1 million, during the first 10 years after implementation, provides efficiencies and improves marketing and communications, past performance measures, Star Ratings, network adequacy, medical loss ratio reporting, requirements during disasters or public emergencies, D–SNP program, MOOP, as well as cost efficiencies to enrollees for prescription drugs. Additionally, there are a variety of transfers to and from the Federal Government (the Medicare Trust Fund and the United States Treasury) which in aggregate will increase dollar spending by $4.3 to $4.5 billion annually. We estimate that this rule generates $2.0 million in annualized costs, discounted at 7 percent relative to year 2016, over an infinite time horizon.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 22, 2022.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the interim rule amendments to 42 CFR 417.472, 422.152, 422.166, 422.252, 423.182, and 423.186, which published at 85 FR 19230 (April 6, 2020) and 85 FR 54820 (September 2, 2020), are adopted as final and the Centers for Medicare & Medicaid Services further amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended by—
■ a. In the definition of ''Fully integrated dual eligible special needs plan'':
■ i. Revising paragraphs (2) and (3);
■ ii. Removing the period at the end of paragraph (4) and adding a semicolon in its place; and
■ iii. Adding paragraphs (5) and (6); and
■ b. Revising the definition of ''Highly integrated dual eligible special needs plan''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Fully integrated dual eligible special needs plan * * *

(2) Whose capitated contract with the State Medicaid agency requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a fully integrated dual eligible special needs plan (FIDE SNP) in the State, except as approved by CMS under § 422.107(g) and (h):

(i) Primary care and acute care, and for plan year 2025 and subsequent years including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries;

(ii) Long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the plan year;

(iii) For plan year 2025 and subsequent years, behavioral health services;

(iv) For plan year 2025 and subsequent years, home health services as defined in § 440.70 of this chapter; and

(v) For plan year 2025 and subsequent years, medical supplies, equipment, and appliances, as described in § 440.70(b)(3) of this chapter;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries;

* * * * *

(5) For plan year 2025 and subsequent years, that has exclusively aligned enrollment; and

(6) For plan year 2025 and subsequent years, whose capitated contract with the State Medicaid agency covers the entire service area for the dual eligible special needs plan.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements—

(1) The capitated contract is between the State Medicaid agency and—

(i) The MA organization; or

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization;

(2) The capitated contract requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State, except as approved by CMS under § 422.107(g) or (h):

(i) Long-term services and supports, including community-based long-term services and supports and some days of coverage of nursing facility services during the plan year; or

(ii) Behavioral health services; and

(3) For plan year 2025 and subsequent years, the capitated contract covers the entire service area for the dual eligible special needs plan.

* * * * *

■ 3. Section 422.100 is amended by—
■ a. In paragraph (f)(4), removing the word ''incurred'' and adding in its place the word ''accrued''.
■ b. In paragraph (f)(5)(iii), removing the word ''incurred'' and adding in its place the word ''accrued''.
■ c. Revising paragraphs (m)(1) introductory text and (m)(2) introductory text;
■ d. Removing paragraph (m)(2)(ii)(B);
■ e. Redesignating paragraph (m)(2)(ii)(A) as paragraph (m)(2)(ii);
■ f. Revising paragraphs (m)(3) and (4) and (m)(5)(i); and
■ g. Adding paragraph (m)(6).

The revisions and addition read as follows:

§ 422.100 General requirements.

* * * * *

(m) * * *

(1) *Access to covered benefits during disasters or emergencies.* When a disaster or emergency is declared as described in paragraph (m)(2) of this section and there is disruption of access to health care as described in paragraph (m)(6) of this section, an MA organization offering an MA plan must, until the end date specified in paragraph (m)(3) of this section occurs,

ensure access to covered benefits in the following manner:

* * * * *

(2) *Declarations of disasters or emergencies.* A declaration of a disaster or emergency will identify the geographic area affected by the event and may be made as one of the following:

* * * * *

(3) *End of the special requirements for the disaster or emergency.* An MA organization must continue furnishing access to benefits as specified in paragraphs (m)(1)(i) through (iv) of this section for 30 days after the conditions described in paragraph (m)(3)(i) or (ii) of this section occur with respect to all applicable emergencies or after the condition described in paragraph (m)(3)(iii) of this section occurs, whichever is earlier:

(i) All sources that declared a disaster or emergency that include the service area declare an end.

(ii) No end date was identified as described in paragraph (m)(3)(i) of this section, and all applicable emergencies or disasters declared for the area have ended, including through expiration of the declaration or any renewal of such declaration.

(iii) There is no longer a disruption of access to health care as defined in paragraph (m)(6) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the disaster or emergency as described in paragraph (m)(3)(i) or (ii) of this section must notify CMS.

(5) * * *

(i) Indicate the terms and conditions of payment during the disaster or emergency for non-contracted providers furnishing benefits to plan enrollees residing in the affected service area(s).

* * * * *

(6) *Disruption of access to health care.* A disruption of access to health care for the purpose of paragraph (m) of this section is an interruption or interference in the service area (as defined at § 422.2) such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services to enrollees, resulting in MA plans failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

■ 4. Section 422.101 is amended by—

■ a. In paragraph (d)(4), removing ''(d)(3)'' and ''incurred'' and adding in their places ''(3)'' and ''accrued'', respectively.

■ b. Revising paragraph (f)(1)(i).

The revision reads as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) * * *

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals' individualized care plan as required under paragraph (f)(1)(ii) of this section. Beginning in 2024, the comprehensive risk assessment tool must include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on each of the following domains:

(A) Housing stability;

(B) Food security; and

(C) Access to transportation.

* * * * *

■ 5. Section 422.107 is amended by—

■ a. Revising the section heading and paragraphs (c)(6) and (d);

■ b. Redesignating paragraph (e) as paragraph (i); and

■ c. Adding new paragraph (e) and paragraphs (f) through (h).

The revisions and additions read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

* * * * *

(c) * * *

(6) The verification of an enrollee's Medicaid eligibility.

* * * * *

(d) *Additional minimum contract requirement.* (1) For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, except as specified in paragraph (d)(2) of this section, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with the requirement in this paragraph (d)(1).

(2) For a dual eligible special needs plan that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries who are not entitled to full medical assistance under a State plan under title XIX of the Act, paragraph (d)(1) of this section does not apply if the SNP operates under the same parent organization and in the same service area as a dual eligible special needs plan limited to beneficiaries with full medical assistance under a State plan under title XIX of the Act that meets the requirements at paragraph (d)(1) of this section.

(e) *Additional opportunities in certain integrated care programs.* (1) CMS facilitates operationalization as described in paragraphs (e)(2) and (3) of this section if a State Medicaid agency requires MA organizations offering dual eligible special needs plans with exclusively aligned enrollment to do both of the following:

(i) Apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more dual eligible special needs plans with a service area limited to that State.

(ii) Use required materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of this chapter.

(2) The requirements, processes, and procedures applicable to dual eligible special needs plans and the MA program, including for applications, bids, and contracting procedures under §§ 422.250 through 422.530, remain applicable. Because implementation of the contract provisions described in paragraph (e)(1) of this section may require administrative steps that cannot be completed between reviewing the contract and the start of the plan year, CMS begins good faith work following receipt of a letter from the State Medicaid agency indicating intent to include the provisions described in paragraph (e)(1) of this section in a future contract year and collaborate with CMS on implementation.

(3) When the conditions of paragraph (e)(1) of this section are met—

(i) Following a State request, CMS grants access for State Medicaid agency officials to the Health Plan Management

System (HPMS) (or its successor) for purposes of oversight and information-sharing related to the MA contract(s) described in paragraph (e)(1)(i) of this section, as long as State Medicaid agency officials agree to protect the proprietary nature of information to which the State Medicaid agency may not otherwise have direct access. State access to the Health Plan Management System (or its successor) is subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. CMS may terminate a State official's access to the Health Plan Management System (or its successor) if any policy is violated or if information is not adequately protected; and

(ii) CMS coordinates with States on program audits, including information-sharing on major audit findings and coordination of audits schedules for the D–SNPs subject to paragraph (e)(1) of this section.

(f) *Enrollee advisory committee.* Any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization in that State.

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

(2) The enrollee advisory committee may also advise managed care plans that serve D–SNP enrollees under title XIX of the Act offered by the same parent organization as the MA organization offering the D–SNP.

(g) *Permissible carve-outs of long-term services and supports for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of long-term services and supports, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use long-term services and supports; or

(2) Constitute a small part of the total scope of long-term services and supports provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(h) *Permissible carve-outs of behavioral health services for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of behavioral health services, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use behavioral health services; or

(2) Constitute a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

* * * * *

■ 6. Section 422.116 is amended by revising paragraph (a)(1)(ii) and adding paragraph (d)(7) to read as follows:

§ 422.116 Network adequacy.

(a) * * *

(1) * * *

(ii) Beginning with contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

* * * * *

(d) * * *

(7) *New or expanding service area applicants.* Beginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use a Letter of Intent (LOI), signed by both the MA organization (MAO) and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of LOIs no longer apply and if the application is approved, the MA organization must be in full compliance with this section, including having signed contracts with the provider or facility.

* * * * *

§ 422.164 [Amended]

■ 7. Section 422.164 is amended by removing and reserving paragraph (i).

■ 8. Section 422.166 is amended by—

■ a. Revising paragraph (a)(2)(i);

■ b. Adding paragraph (i)(12); and

■ c. Removing and reserving paragraphs (j)(1)(v) and (j)(2).

The revision and addition read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and Part D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) * * *

(12) *Special rules for the 2023 Star Ratings only.* For the 2023 Star Ratings only, for measures derived from the Health Outcomes Survey only, CMS does not apply the provisions in paragraph (i)(9) or (10) of this section and CMS does not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

■ 9. Section 422.252 is amended by revising the definition of ''New MA plan'' to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a MA contract offered by a parent organization that has

not had another MA contract in the previous 3 years. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

* * * * *

■ 10. Section 422.502 is amended by revising paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions for any one contract.

(*1*) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(*2*) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

* * * * *

■ 11. Section 422.503 is amended by revising paragraphs (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(5) * * *

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

* * * * *

■ 12. Section 422.504 is amended by revising paragraph (m) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(m) *Issuance of compliance actions for failure to comply with the terms of the contract.* The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the MA organization.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.

(iv) The history of prior offenses by the MA organization or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are requested for particularly serious or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 13. Section 422.530 is amended by revising paragraph (c)(4) to read as follows:

§ 422.530 Plan crosswalks.

* * * * *

(c) * * *

(4) When—

(i) A renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For the crosswalk exception in this paragraph (c)(4)(i), CMS does not permit enrollees to be moved between different contracts; or

(ii) An MA organization creates a new MA contract when required by a State as described in § 422.107(e), eligible enrollees may be moved from the existing D–SNP that is non-renewing, reducing its service area, or has its eligible population newly restricted by a State, to a D–SNP offered under the D–SNP-only contract, which must be of the same plan type operated by the same parent organization. For the crosswalk exception in this paragraph (c)(4)(ii), CMS permits enrollees to be moved between different contracts.

* * * * *

■ 14. Section 422.561 is amended by revising the definition of ''Applicable integrated plan'' to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means either of the following:

(1) *Before January 1, 2023.* (i) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(ii) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

(2) *On or after January 1, 2023.* (i)(A) A fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(B) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization; or

(ii) A dual eligible special needs plan and affiliated Medicaid managed care plan where—

(A) The dual special needs plan, by State policy, has enrollment limited to those beneficiaries enrolled in a Medicaid managed care organization as described in paragraph (2)(ii)(B) of this definition;

(B) There is a capitated contract between the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization; and

(*1*) A Medicaid agency; or

(*2*) A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

(C) Through the capitated contract described in paragraph (2)(ii)(B) of this definition, Medicaid benefits including primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and at a minimum, one of the following: Home health services as defined in § 440.70 of this chapter, medical supplies, equipment, and appliances as described in § 440.70(b)(3) of this chapter, or nursing facility services are covered for the enrollees.

* * * * *

■ 15. Section 422.629 is amended by—

■ a. Revising paragraph (d);

■ b. In paragraph (k)(4)(ii), removing the phrase ''integrated organization determination decision'' and adding in its place the phrase ''integrated reconsideration determination'';

■ c. Revising paragraph (l)(1); and

■ d. Adding paragraph (l)(4).

The revisions and addition read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

* * * * *

(l) * * *

(1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee's representative, including any person authorized under State law.

* * * * *

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

■ 16. Section 422.631 is amended by adding paragraph (d)(3) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(d) * * *

(3) *Timeframe for requests for payment.* The applicable integrated plan must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

* * * * *

■ 17. Section 422.633 is amended by revising the section heading and paragraphs (e)(1) and (f)(3)(i) introductory text to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(e) * * *

(1) Applicable integrated plans must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider making the request on behalf of an enrollee, when the request is not a request for expedited payment.

* * * * *

(f) * * *

(3) * * *

(i) The applicable integrated plan may extend the timeframe for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

* * * * *

■ 18. Section 422.634 is amended by revising paragraph (d) to read as follows:

§ 422.634 Effect.

* * * * *

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

* * * * *

■ 19. Section 422.2260 is amended by adding the definition of ''Third-party marketing organization (TPMO)'' in alphabetical order to read as follows:

§ 422.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) means organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.

■ 20. Section 422.2265 is amended by adding paragraphs (b)(13) and (14) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(13) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form–1696).

(14) Enrollment instructions and forms.

* * * * *

■ 21. Section 422.2267 is amended by—

■ a. Redesignating paragraphs (e)(30) through (38) as paragraphs (e)(32) through (40).

■ b. Adding new paragraphs (e)(30) and (31) and paragraph (e)(41).

The additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(30) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 422.111(i). The member ID card—

(i) Must be provided to new enrollees within ten calendars days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the plan effective date, whichever is later;

(ii) Must include the plan's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 422.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a PPO and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(31) *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone material, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. The disclaimer consists of the statement: ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1–800–MEDICARE to get information on all of your options.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization unless the TPMO sells all commercially available MA plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

■ 22. Section 422.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 422.504(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, MA plans must implement the following as a part of their oversight of TPMOs:

(1) When a TPMO is not otherwise an FDR, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to the MA plan.

(2) Contracts, written arrangements, and agreements between the TPMO and an MA plan, or between the TPMO and an MA plan's FDR, must ensure the TPMO:

(i) Discloses to the MA organization any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Records all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Reports to plans monthly any staff disciplinary actions or violations of any requirements that apply to the MA plan associated with beneficiary interaction to the plan.

(iv) Uses the TPMO disclaimer as required under § 422.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally when communicating with a beneficiary through telephone.

(B) In writing when communicating with a beneficiary through mail or other paper.

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

■ 23. Section 422.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

(b) For contract years 2018 through 2022, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to an MA organization that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

■ 24. Section 422.2490 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i) and adding paragraph (b)(2)(ii) to read as follows:

§ 422.2490 Release of Part C MLR data.

* * * * *

(b) * * *

(2) * * *

(ii) Amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 25. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 26. Section 423.100 is amended by adding in alphabetical order the definition of ''Price concession'' to read as follows:

§ 423.100 Definitions.

* * * * *

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

* * * * *

■ 27. Effective January 1, 2024, § 423.100 is further amended by removing the definition of ''Negotiated prices'' and adding in alphabetical order the definition of ''Negotiated price'' to read as follows:

§ 423.100 Definitions.

* * * * *

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

* * * * *

§ 423.184 [Amended]

■ 28. Section 423.184 is amended by removing and reserving paragraph (i).

■ 29. Section 423.186 is amended by—

■ a. Revising paragraphs (a)(2)(i) and (i)(9); and

■ b. Removing and reserving paragraph (j)(1)(iv).

The revisions read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years of the program.

* * * * *

(i) * * *

(9) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(7) or (8) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

■ 30. Section 423.503 is amended by revising the section heading and paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if a Part D plan sponsor fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(C) Filed for or is currently under state bankruptcy proceedings.

(D) Received any combination of Part C or Part D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions on any one contract.

(*1*) CMS determines the number of points each Part D plan sponsor accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 423.505(n) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 423.505(n) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 423.505(n) counts for 1 point.

(*2*) CMS adds all the point values for each Part D plan sponsor to determine if any organization meets CMS' identified threshold.

* * * * *

■ 31. Section 423.505 is amended by revising paragraph (n) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(n) *Issuance of compliance actions for failure to comply with the terms of the contract.* The Part D plan sponsor acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (n)(3) of this section if it determines that the Part D plan sponsor has not complied with the terms of a current or prior Part D contract with CMS.

(i) CMS may determine that a Part D plans sponsor is out of compliance with a Part D requirement when the organization fails to meet performance standards articulated in the Part D statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D plan sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D plan sponsors.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the Part D plan sponsor.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the Part D plan sponsor.

(iv) The history of prior offenses by the Part D plan sponsor or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the Part D plan sponsor's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are issued for particularly serious and/or continued noncompliance with the requirements of the Part D plan sponsors' current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the Part D plan sponsor has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance,

and/or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 32. Section 423.2260 is amended by adding the definition of ''Third-party marketing organization (TPMO)'' in alphabetical order to read as follows:

§ 423.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) are organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of a Part D plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 423.4, but may also be entities that are not FDRs but provide services to a Part D sponsor or a Part D sponsor's FDR.

■ 33. Section 423.2265 is amended by adding paragraphs (b)(14) and (15) to read as follows:

§ 423.2265 Websites.

* * * * *

(b) * * *

(14) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form-1696).

(15) Enrollment instructions and forms.

* * * * *

■ 34. Section 423.2267 is amended by—

■ a. Redesignating paragraphs (e)(32) through (37) as paragraphs (e)(34) through (39); and

■ b. Adding new paragraphs (e)(32) and (33) and paragraphs (e)(40) and (41).

The additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(32) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 423.128(d)(2). The member ID card—

(i) Must be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by the last day of month prior to the plan effective date, whichever is later;

(ii) Must include the Part D sponsor's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 423.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a preferred provider organization (PPO) and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(33) *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(40) *Limited access to preferred cost-sharing pharmacies.* This is standardized content that must—

(i) Be used on all materials mentioning preferred pharmacies when there is limited access to preferred pharmacies; and

(ii) Include the following language: ''<insert organization/plan name>'s pharmacy network includes limited lower-cost, preferred pharmacies in <insert geographic area type(s) and state(s) for which plan is an outlier)>. The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including whether there are any lower-cost preferred pharmacies in your area, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>.''

(41) *Third-party marketing organization disclaimer.* This is standardized content. The disclaimer consists of the statement: ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1–800–MEDICARE to get information on all of your options.'' The Part D sponsor must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 423.2260, that sells plans on behalf of more than one Part D sponsor unless the TPMO sells all commercially available Part D plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any TPMO marketing materials, including print materials and television advertising.

■ 35. Section 423.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 423.505(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, Part D sponsor must implement the following as a part of their oversight of TPMOs:

(1) When TPMOs is not otherwise an FDR, the Part D sponsor is responsible for ensuring that the TPMO adheres to any requirements that apply to the Part D sponsor.

(2) Contracts, written arrangements, and agreements between the TPMO and a Part D plan, or between a TPMO and a Part D plan's FDR, must ensure the TPMO:

(i) Discloses to the plan any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Report to plans monthly any staff disciplinary actions or violations of any requirements that apply to the Part D sponsor associated with beneficiary interaction to the plan.

(iv) Use the TPMO disclaimer as required under § 423.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for a Part D sponsor, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided:

(A) Verbally when communicating with a beneficiary through telephone;

(B) In writing when communicating with a beneficiary through mail or other paper; and

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) When applicable, disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

■ 36. Effective January 1, 2024, § 423.2305 is amended by—

■ a. Revising paragraphs (1) and (2) of the definition of ''Negotiated price''; and

■ b. Designating the undesignated paragraph following the definition of ''Negotiated price'' as paragraph (4).

The revisions read as follows:

§ 423.2305 Definitions.

* * * * *

Negotiated price * * *

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and

(ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, non-pharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

* * * * *

■ 37. Section 423.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 423.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the Part D sponsor to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for prescription drugs, supplemental benefits, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract years 2018 through 2022, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to a Part D sponsor that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

Dated: April 27, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–09375 Filed 4–29–22; 4:15 pm]

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FEDERAL REGISTER

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Part III

The President

Federal Register
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Monday, May 9, 2022

Presidential Documents

Title 3—

The President

Proclamation 10389 of May 4, 2022

Missing or Murdered Indigenous Persons Awareness Day, 2022

By the President of the United States of America

A Proclamation

For generations, Indigenous persons, including American Indians, Alaska Natives and Native Hawaiians, have been forced to mourn a missing or murdered loved one without the answers and support they deserve. On Missing or Murdered Indigenous Persons Awareness Day, we remember these victims and their families, and commit to working with Tribal Nations and Native communities to achieve justice and healing.

The Federal Government has an obligation to ensure that cases of missing or murdered persons are met with swift and effective action. My Administration is fully committed to investigating and resolving these cases through a coordinated law enforcement response, as well as intervention and prevention efforts. We are also dedicated to researching the underlying causes of this violence and to working with Native communities to address them.

The safety and well-being of all Native Americans continues to be a top priority for my Administration. That is why during my first year in office, at the first White House Tribal Nations Summit, I issued an Executive Order directing Federal agencies to improve public safety and criminal justice for Native Americans and to address the crisis of missing or murdered Indigenous people. This includes implementing a coordinated Federal law enforcement strategy that supports Tribal and other local law enforcement efforts. It also strengthens prevention, early intervention, and survivor services while improving data collection, analysis, and information sharing.

For far too long, justice for Indigenous communities has been elusive. We must improve our investigations to resolve missing or murdered cases while supporting victims and their families. Toward that aim, the Department of Justice is working closely with Tribal Nations to develop regionally appropriate guidelines for these cases. The Department of Justice has created a dedicated steering committee to oversee and coordinate this critical work, including an outreach services liaison for Federal criminal cases in Indian Country.

This March, I signed into law the Violence Against Women Act Reauthorization Act of 2022. This important law expands special criminal jurisdiction of Tribal courts to cover non-Native perpetrators of sexual assault, child abuse, stalking, sex trafficking, and assaults on Tribal law enforcement officers on Tribal lands and supports the development of a pilot project to enhance access to safety for survivors in Alaska Native villages.

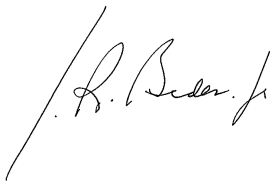
My Administration understands that Native people, particularly survivors of violence, know best what their communities need to feel safe. That is why we must work hand in hand with Tribal partners through each phase of the justice system to create solutions that are victim-centered, trauma-informed, and culturally appropriate.

Our Nation's failure to address this ongoing tragedy not only demeans the dignity of each Indigenous person who goes missing or is murdered—it undermines the humanity of us all. Today and every day, we must continue to stand up for Indigenous people, and we must never forget the thousands

of unsolved cases that continue to cry out for justice and healing. As a Nation, we must answer that call and work together to achieve the promise of America for all Americans.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 5, 2022, as Missing or Murdered Indigenous Persons Awareness Day. I call on all Americans and ask all levels of government to support Tribal governments and Tribal communities' efforts to increase awareness of the issue of missing or murdered Indigenous persons through appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of May, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2022–10073
Filed 5–6–22; 11:15 am]
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Presidential Documents

Proclamation 10390 of May 4, 2022

National Day of Prayer, 2022

By the President of the United States of America

A Proclamation

Throughout our history, prayer has been an anchor for countless Americans searching for strength and wisdom in times of struggle and sharing hope and gratitude in seasons of joy. In public reflections on life's many blessings and in quiet moments during life's most difficult trials, Americans of nearly every background and faith have turned to prayer for comfort and inspiration. Prayer is a sacred right protected by free speech and religious liberty enshrined in our Constitution, and it continues to lift our spirits as we navigate the challenges of our time.

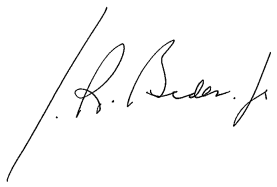
On this day, we recognize the healing power of prayer, especially as we recover from the trauma and loss of the COVID–19 pandemic. Today we find ourselves in a moment of renewal—of lives saved, of new jobs created, and of new hope for rebuilding America. Today is also a moment of reflection when we are called to address some of the greatest challenges humanity has ever faced—saving our planet from the existential threat of climate change; responding to attacks on democracy at home and abroad; and living up to our Nation's promise of liberty, justice, and equality for all.

As the late President Dwight D. Eisenhower once said, ''There is a need we all have in these days and times for some help which comes from outside ourselves.'' Across our diverse and cherished beliefs, on this National Day of Prayer, no matter how or whether we pray, we are all called to look outside ourselves. Let us find in our hearts and prayers the determination to put aside our differences, come together, and truly see one another as fellow Americans.

The Congress, by Public Law 100–307, as amended, has called on the President to issue each year a proclamation designating the first Thursday in May as a ''National Day of Prayer.''

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 5, 2022, as a National Day of Prayer. I call upon the citizens of our Nation to give thanks, in accordance with their own faiths and consciences, for our many freedoms and blessings, and I invite all people of faith to join me in asking for God's continued guidance, mercy, and protection.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of May, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-sixth.



[FR Doc. 2022–10075
Filed 5–6–22; 11:15 am]
Billing code 3395–F2–P

Presidential Documents

Executive Order 14073 of May 4, 2022

Enhancing the National Quantum Initiative Advisory Committee

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 104(a) of the National Quantum Initiative Act (Public Law 115–368) (NQI Act), and section 301 of title 3, United States Code, and in order to ensure continued American leadership in quantum information science and its technology applications, it is hereby ordered as follows:

Section 1. *Purpose.* Quantum information science (QIS) can enable transformative advances in knowledge and technology for industry, academia, and government. Accordingly, the National Quantum Initiative (NQI), which aims to ensure the continued leadership of the United States in QIS and its technology applications, is a substantial and sustained national priority. The NQI Program, established pursuant to section 101 of the NQI Act, encompasses contributions from across the Federal Government, as exemplified by the QIS research, development, demonstration, and training activities pursued by executive departments and agencies (agencies) with membership on either the National Science and Technology Council (NSTC) Subcommittee on Quantum Information Science (SCQIS) or the NSTC Subcommittee on Economic and Security Implications of Quantum Science (ESIX).

Sec. 2. *Establishment.* (a) To ensure that the NQI Program and the Nation are informed by evidence, data, and perspectives from a diverse group of experts and stakeholders, the National Quantum Initiative Advisory Committee (Committee) is hereby established. Consistent with the NQI Act, the Committee shall advise the President, the SCQIS, and the ESIX on the NQI Program.

(b) The Committee shall consist of the Director of the Office of Science and Technology Policy (Director) or the Director's designee and not more than 26 members, appointed by the President, who are United States citizens representative of industry, universities, and Federal laboratories, and who are qualified to provide advice and information on QIS and technology research, development, demonstrations, standards, education, technology transfer, commercial application, or national security and economic concerns.

(c) The Committee shall have two Co-Chairs. The Director or the Director's designee shall serve as one Co-Chair of the Committee. The President shall designate another Co-Chair from among the appointed members to serve as Co-Chair with the Director.

Sec. 3. *Functions.* (a) The Committee shall advise the President and the SCQIS and the ESIX (Subcommittees) and make recommendations for the President to consider when reviewing and revising the NQI Program. The Committee shall also carry out all responsibilities set forth in section 104 of the NQI Act.

(b) The Committee shall meet at least twice a year and shall:

(i) respond to requests from the President or the Co-Chairs of the Committee for information, analysis, evaluation, or advice relating to QIS and its technology applications;

(ii) solicit information and ideas from a broad range of stakeholders on QIS, including the research community, the private sector, academia, national laboratories, agencies, State and local governments, foundations, and nonprofit organizations;

(iii) review the national strategy for QIS; and

(iv) respond to requests from the Subcommittees.

Sec. 4. *Administration.* (a) The heads of agencies shall, to the extent permitted by law, provide the Committee with information concerning QIS and its technology applications when requested by a Committee Co-Chair.

(b) The Co-Chairs of the Committee may establish standing subcommittees and ad hoc groups, including technical advisory groups, to assist and provide information to the Committee.

(c) The Director may request that members of the Committee, standing subcommittees, or ad hoc groups who do not hold a current clearance for access to classified information receive appropriate clearances and access determinations pursuant to Executive Order 13526 of December 29, 2009 (Classified National Security Information), as amended, or any successor order.

(d) The National Quantum Coordination Office shall provide technical and administrative support to the Committee, pursuant to section 102(b) of the NQI Act.

(e) Committee members shall serve without any compensation for their work on the Committee, but may receive travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707).

Sec. 5. *Revocation.* Executive Order 13885 of August 30, 2019 (Establishing the National Quantum Initiative Advisory Committee), is hereby revoked.

Sec. 6. *General Provisions.* (a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (FACA), may apply to the Committee, any functions of the President under the FACA, except for those in section 6 of the FACA, shall be performed by the Secretary of Energy, in consultation with the Director, in accordance with the guidelines and procedures established by the Administrator of General Services.

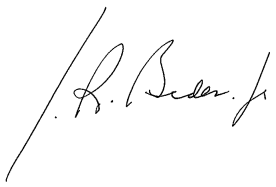
(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 4, 2022.

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FEDERAL REGISTER

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No. 89 May 9, 2022

Part IV

The President

Proclamation 10391—Military Spouse Appreciation Day, 2022

Federal Register
Vol. 87, No. 89
Monday, May 9, 2022

Presidential Documents

Title 3—

The President

Proclamation 10391 of May 5, 2022

Military Spouse Appreciation Day, 2022

By the President of the United States of America

A Proclamation

Military spouses are the rock on which their families, our military community, and our national security depend. Though most do not wear a uniform themselves, they serve and strengthen our Nation every day—providing our brave troops with support, comfort, and love. They build communities of strength on bases around the world to care for our military family, pitching in wherever they see a need that is unmet. On Military Spouse Appreciation Day, we recognize the nearly one million military spouses and their vital contributions to our Nation. We are grateful for their selfless sacrifice and inspired by their strength, fortitude, and courage.

Today, America's military spouses are a constellation of diverse individuals with unique backgrounds and the common attribute of uncommon resilience. Like their service members, they too represent the best of who we are as Americans. Military spouses know what it means to make sacrifices in defense of our ideals and freedoms. And they live with the hardship of having their life partner deployed away from home—juggling all the responsibilities of work and family while saying an extra prayer every morning that their spouse returns home safely.

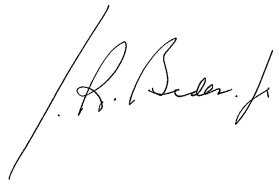
Even during the most demanding circumstances, military spouses continue to serve, creating innovative solutions to meet the challenges we face as a Nation. Today, military spouses serve in dynamic leadership roles across all sectors—using their own experiences to support the needs of the communities around them. With enthusiasm and an entrepreneurial spirit, military spouses create businesses and support systems that serve the needs of others.

The Biden family is a military family, and caring for our Nation's military spouses is something that Jill and I both deeply understand. While our Nation can never fully repay the debt we owe to our service members and their families, caregivers, and survivors, it is our sacred obligation to make sure that they receive the care and support they have earned. Through the First Lady's Joining Forces initiative, my Administration is strengthening support for military families in three critical areas: military spouse employment and entrepreneurship, military child education, and the well-being of military families. We continue to seek new and better ways to do more to address the needs of our military families, especially responding to the needs of military spouses with resources and services that allow them to thrive in all aspects of life.

On Military Spouse Appreciation Day and every day, we are grateful for the extraordinary service and sacrifice of America's military spouses. May we continue to lift their voices, invest in their talents, and respond to their unique needs in ways that ease their challenges and enable them to reach their goals and aspirations. May God bless our military families, caregivers, and survivors, and may God protect our troops.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 6, 2022, as Military Spouse Appreciation Day. I call upon the people of the United States to honor military spouses with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of May, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-sixth.



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