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COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 160

RIN 3038–AE80

Privacy of Consumer Financial Information—Amendment To Conform Regulations to the Fixing America's Surface Transportation Act

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is adopting amendments to revise its regulations requiring covered persons to provide annual privacy notices to customers. The revisions implement the Fixing America's Surface Transportation Act's (''FAST Act'') December 2015 statutory amendment to the Gramm-Leach-Bliley Act (''GLB Act'') by providing an exception to the annual notice requirement under certain conditions.

DATES: This final rule is effective May 28, 2019.

FOR FURTHER INFORMATION CONTACT: Matthew Kulkin, Director, (202) 418–5213, *mkulkin@cftc.gov*; Frank Fisanich, Chief Counsel, (202) 418–5949, *ffisanich@cftc.gov*; or Jacob Chachkin, Special Counsel, (202) 418–5496, *jchachkin@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Title V, Subtitle A of the GLB Act [1] (''Title V'') mandates that financial institutions provide their consumers with whom they have customer relationships (''customers'') with annual notices regarding those institutions' privacy policies and practices.[2] Further, subject to certain exceptions, if financial institutions share nonpublic personal information with particular types of third parties, the financial institutions must also provide their consumers with an opportunity to opt out of the sharing.[3] The Commission and entities subject to its jurisdiction were originally excluded from Title V's coverage.[4] However, section 124 of the Commodity Futures Modernization Act of 2000 [5] amended the Commodity Exchange Act (''CEA'') to add section 5g,[6] providing that futures commission merchants (''FCMs''), commodity trading advisors (''CTAs''), commodity pool operators (''CPOs''), and introducing brokers (''IBs'') [7] fall under the requirements of Title V and requiring the Commission to prescribe regulations in furtherance of Title V. Thus, in 2001, the Commission promulgated part 160 of its regulations to establish standards relating to Title V.[8]

Consistent with Title V, part 160 requires that, generally, all FCMs, RFEDs, CTAs, CPOs, IBs, MSPs, and SDs that are subject to the jurisdiction of the Commission, regardless of whether they are required to register with the Commission (''Covered Persons''), provide a clear and conspicuous notice to customers that accurately reflects their privacy policies and practices not less than annually during the life of the customer relationship.[9]

On December 4, 2015, Congress amended Title V as part of the FAST Act.[10] This amendment, titled ''Eliminate Privacy Notice Confusion,'' added section 503(f) to the GLB Act to limit the circumstances under which a financial institution must provide a privacy notice to its customers on an annual basis.[11] In particular, under section 503(f), a financial institution is excepted from the requirement to send privacy notices on an annual basis if that financial institution (1) does not share nonpublic personal information except as described in certain specified exceptions; and (2) has not changed its policies and practices with regard to disclosing nonpublic personal information from those policies and practices that the institution disclosed in the most recent disclosure it sent to consumers in accordance with section 503.[12] This amendment to the GLB Act became effective upon enactment of the FAST Act in December 2015.

II. Proposal

On December 10, 2018, the Commission published a Notice of Proposed Rulemaking (the ''NPRM'') [13] to amend § 160.5 of the Commission's regulations (the ''Proposal'') to implement the FAST Act amendments to the GLB Act with respect to Covered Persons.[14] Specifically, the Commission proposed to modify § 160.5(a) to add a reference to an exception, contained in

[1] Title V, Subtitle A, Public Law 106–102, 113 Stat. 1338 (1999), as codified at 15 U.S.C. 6801–6809.

[2] *See* 15 U.S.C. 6803.

[3] *See* 15 U.S.C. 6802(b). *See also* 15 U.S.C. 6809(4)(A) (defining ''nonpublic personal information'').

[4] 15 U.S.C. 6809(3)(B).

[5] Section 124, Appendix E of Public Law 106–554, 114 Stat. 2763 (2000).

[6] 7 U.S.C. 7b–2.

[7] For the definitions of these intermediary categories, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[8] Privacy of Customer Information, 66 FR 21235 (April 27, 2001). The Commission later modified its part 160 regulations to apply them to retail foreign exchange dealers (''RFEDs''), swap dealers (''SDs''), and major swap participants (''MSPs''). Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55409 (Sept. 10, 2010) for RFEDs, and Privacy of Consumer Financial Information; Conforming Amendments Under Dodd-Frank Act, 76 FR 43874 (July 22, 2011) for SDs and MSPs. For the definition of RFED, *see* § 5.1(h). 17 CFR 5.1(h). For the definitions of SD and MSP, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[9] 17 CFR 160.1 and 160.5. Part 160 does not apply to foreign (non-resident) FCMs, RFEDs, CTAs, CPOs, IBs, MSPs, and SDs that are not registered with the Commission. 17 CFR 160.1. Therefore, they are not ''Covered Persons'' as defined in this release.

[10] Section 75001, Public Law 114–94, 129 Stat. 1312 (2015), available at *http://transportation.house.gov/uploadedfiles/fastact_xml.pdf* (last visited Nov. 30, 2018).

[11] *Id.*

[12] *See* 15 U.S.C. 6803(f).

[13] 83 FR 63450 (Dec. 10, 2018).

[14] In developing the Proposal, pursuant to Section 6804(a)(2) of the GLB Act, the Commission consulted and coordinated with the Bureau of Consumer Financial Protection (''CFPB''), the Securities and Exchange Commission, the Federal Trade Commission, and the National Association of Insurance Commissioners regarding consistency and comparability with the regulations prescribed by such agencies. *See* 15 U.S.C. 6804(a)(2). In addition, the Proposal was consistent with rules recently finalized by the CFPB (''CFPB Final Rule''). *See* Amendment to the Annual Privacy Notice Requirement Under the Gramm-Leach-Bliley Act (Regulation P), 83 FR 40945 (Aug. 17, 2018).

a new paragraph (d), to the requirement that a Covered Person annually provide a clear and conspicuous notice to customers that reflects the Covered Person's privacy policies and practices (''annual privacy notice'') during the life of the customer relationship. The Commission proposed to describe that exception in Section 160.5(d)(1) by stating that a Covered Person is not required to deliver an annual privacy notice to customers pursuant to § 160.5(a) if it: (1) Provides nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of §§ 160.13, 160.14, 160.15 and any other exceptions adopted by the Commission pursuant to section 504(b) of the GLB Act; [15] and (2) has not changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 160.6(a)(2) through (5) and § 160.6(a)(9) [16] in the most recent privacy notice provided to such customer pursuant to part 160 of the Commission's regulations.

In addition, because, as discussed in the Proposal, the GLB Act is silent as to when a financial institution that has relied on and no longer meets the requirements of the exception must next provide an annual privacy notice, the Commission proposed a framework for these circumstances. Specifically, proposed § 160.5(d)(2) stated that a Covered Person who has been excepted from delivering an annual privacy notice pursuant to § 160.5(d)(1) and who changes its policies or practices in such a way that it no longer meets the requirements for that exception, would, if such a change required a revised privacy notice pursuant to § 160.8,[17] be required to provide an annual privacy notice in accordance with the timing requirements in § 160.5(a), treating the revised privacy notice as an initial privacy notice. Further, if the change in policies or practices did not require a revised privacy notice pursuant to § 160.8 to be sent, a Covered Person who has been previously excepted from delivering an annual privacy notice would be required to provide an annual privacy notice to customers within 100 days of the change in their policies or practices.[18]

As discussed in the Proposal, the Commission proposed this 100-day period because the Commission believes the annual privacy notice should be delivered within a relatively short time so that customers are informed of the change in a timely manner. Further, the Commission stated its belief that 100 days would allow a Covered Person to meet the notice requirement without imposing additional costs on Covered Persons; particularly, a 100-day delivery period would accommodate the inclusion of the notice with their quarterly statements.[19] In addition, this 100-day delivery period is required under the CFPB Final Rule, and the Commission stated that proposing the same delivery requirement as the CFPB furthers the Commission's goal of having its regulations be consistent with those of other regulators, where appropriate.

In order to ensure that the Proposal, if adopted, achieved its stated purpose, the Commission requested comments generally on all aspects of the Proposal and the NPRM,[20] as well as comments on certain specific matters discussed below. The comment period for the Proposal ended on February 8, 2019.

III. Summary of Comments and Final Rule

The Commission received one relevant comment,[21] which was supportive of the Proposal.

The Commission is adopting the final rule (''Final Rule'') as proposed. Accordingly, the Commission is adopting the amendments to Commission regulation 160.5 as shown in the rule text in this document and for the reasons discussed in the Proposal and reiterated above.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act [22] (''RFA'') requires federal agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities. In the Proposal, the Commission certified that the Proposal would not have a significant economic impact on a substantial number of small entities. The Commission requested comments with respect to the RFA and received no such comments.

As discussed in the Proposal, the Final Rule adds an exception to § 160.5's requirement that Covered Persons deliver annual privacy notices, as discussed above. The Final Rule affects Covered Persons (*i.e.,* certain FCMs, RFEDs, CTAs, CPOs, IBs, MSPs, and SDs). To the extent that the Final Rule will impact Covered Persons that may be small entities for purposes of the RFA,[23] the Commission considered

[15] Section 503(f)(1) of the GLB Act permits a financial institution to share nonpublic personal information in accordance with the provisions of sections 502(b)(2) or (e) of the GLB Act or regulations prescribed under section 504(b) of the GLB Act. *See* 15 U.S.C. 6802 and 6803. Sharing by a financial institution, as described in sections 502(b)(2) or (e), does not trigger the consumer's statutory right to opt out of such sharing. These exceptions are incorporated into existing Commission regulations at 17 CFR 160.13 (Exception to opt out requirements for service providers and joint marketing), 160.14 (Exceptions to notice and opt out requirements for processing and servicing transactions), and 160.15 (Other exceptions to notice and opt out requirements). Section 504(b) of the GLB Act gives the Commission and other relevant agencies authority to include additional exceptions to certain regulations promulgated under Title V as are deemed consistent with Title V's purposes. *See* 15 U.S.C. 6804(b).

[16] Paragraphs (1) through (9) of § 160.6(a) set forth the specific types of information that a Covered Person must include in its privacy notices. 17 CFR 160.6 (a)(1)–(9). As discussed in the Proposal, the information required by § 160.6(a)(2) through (5) and § 160.6(a)(9), which § 160.5(d)(1)(ii) references, specifically relate to the policies and practices connected to disclosing nonpublic personal information. As new GLB Act section 503(f)(2) states that a condition for the annual privacy notice exception is that a financial institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed in the most recent notice sent to consumers, the Commission is framed the scope of the proposed exception to reference only the types of information listed in § 160.6(a)(2) through (5) and § 160.6(a)(9).

[17] 17 CFR 160.8 (Revised privacy notices).

[18] In developing this framework, the Commission looked to § 160.8 because that provision already addresses circumstances in which a Covered Person might change its privacy policies or practices in a way that affects the content of the notices. Specifically, § 160.8 requires that a Covered Person provide a revised notice to consumers before implementing certain types of changes. In other cases, part 160 currently contemplates that a change in policy or practice that affects the content of the notices would simply be reflected on the next regular annual notice provided to customers pursuant to § 160.5. The Commission therefore proposed different timing requirements for resumption of delivery of annual notices, depending on whether the change at issue would trigger the requirement for a revised notice under § 160.8 prior to the change taking effect.

[19] The Commission also noted in the Proposal that a delivery requirement resulting from a change in policies and practices described under proposed Commission regulation 160.5(d)(1)(ii) is effectively a one-time burden for a Covered Person absent additional changes to its policies and practices. Specifically, under the Proposal, after providing the one annual privacy notice, the Covered Person would once again meet both of the conditions for the exception—it would not be sharing other than as described under Commission regulation 160.5(d)(1)(i) and its policies and practices would not have changed since it provided the annual privacy notice. Because the Covered Person would once again meet the conditions for the exception, it would not be required to provide future annual privacy notices.

[20] Proposal, 83 FR at 63453.

[21] The Commission also received one comment that was not relevant to the Proposal. These comments are available at *https://comments.cftc.gov/PublicComments/CommentList.aspx?id=2938*.

[22] 5 U.S.C. 601 *et seq.*

[23] The Commission has previously determined that certain entities are not ''small entities'' for purposes of the RFA. *See, e.g.,* 47 FR 18618, 18619

whether the Final Rule will have a significant economic impact on such Covered Persons.

As a Covered Person may continue to provide annual privacy notices and not avail itself of the exception to the annual privacy notice requirement in § 160.5, the Final Rule will not impose any new regulatory obligations on Covered Persons, including Covered Persons that may be small entities for purposes of the RFA. Rather, to the extent that a Covered person relies on the exception, it would simply avoid providing a privacy notice annually until such time as it is no longer eligible for the exception. The Final Rule's clarification that, once it is no longer eligible for the exception, the Covered Person needs to provide a privacy notice either in accordance with existing § 160.8 or within 100 days also does not result in any new burdens. Sections 160.5 and 160.8 are existing requirements to deliver annual privacy notices and revised privacy notices under certain circumstances. Further, the Commission endeavors to reduce any burdens for those Covered Persons utilizing the exception by allowing the 100-day period following loss of the exception to resume delivery of an annual privacy notice where a notice is not already required pursuant to § 160.8, as discussed above. The Commission does not, therefore, expect that any small entities that may be impacted by the rule to incur any additional costs as a result of the Final Rule.

Therefore, the Commission believes that the Final Rule will not have a significant economic impact on a substantial number of small entities, as defined in the RFA.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the Final Rule will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') [24] imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

As discussed in the Proposal, the Commission believes that the Final Rule will not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of OMB under the PRA. However, by providing the exception to the requirement to provide annual privacy notices to customers discussed above, the Final Rule modifies a collection of information for which the Commission has previously received a control number from OMB. The title for this collection of information is ''Privacy of Consumer Financial Information, OMB control number 3038–0055''.[25] Collection 3038–0055 is currently in force with its control number having been provided by OMB. Accordingly, the Commission submitted to OMB revisions to OMB control number 3038–0055 to reflect the addition of this exception and the resulting reduction of burden. In particular, the Commission estimated that the availability of the exception in Commission regulation 160.5(d) will reduce the current number of annual privacy notices by approximately 30%. Accordingly, in accordance with its previous estimates, the Commission estimated that the Final Rule will reduce the total number of responses by 113,620 responses annually and reduce the time burden by approximately 1,136 hours annually. The Commission believes that the one-time cost of adopting the annual privacy notice exception for Covered Persons that adopt it is de minimis.

Information Collection Comments. In the Proposal, the Commission invited the public and other Federal agencies to comment on any aspect of the information collection requirements discussed therein. The Commission did not receive any such comments.

C. Cost-Benefit Considerations

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) considerations.

As discussed above, the Commission is implementing the FAST Act's amendments to the GLB Act by amending § 160.5 to incorporate an exception to a Covered Person's obligation to provide an annual privacy notice under certain specified circumstances, consistent with section 503(f) of the GLB Act, and address when a Covered Person that has relied on and no longer meets the requirements of that exception must next provide an annual privacy notice.

Below, the Commission discusses the costs and benefits of the Final Rule.[26] The baseline against which the costs and benefits are considered is the current status quo for Covered Persons with respect to their obligation to provide annual privacy notices. The Commission recognizes that there are inherent costs and benefits to Covered Persons and their customers associated with providing an exception to the annual privacy notice requirement, which Congress took into account in amending the GLB Act under the FAST Act. The Commission further recognizes that there are costs and benefits due to discretionary actions taken by the Commission in implementing the exception. In formulating the Final Rule, the Commission was mindful of the policy goals that drove Congress to create this exception and endeavored not to impose unnecessary burdens on Covered Persons in determining when a Covered Person next needs to provide an annual privacy notice after loss of the exception.[27]

(Apr. 30, 1982) (registered FCMs); 75 FR 55410, 55416 (Sept. 10, 2010) (RFEDs); 77 FR 2613, 2620 (Jan. 19, 2012) (SDs and MSPs). However, the Commission has determined that CPOs exempt pursuant to 17 CFR 4.13(a) are small entities. *See* 46 FR 26004 (May 8, 1981); 47 FR at 18619. The definitions of IB and CTA are also broad enough to potentially encompass ''small entities.'' *See* 48 FR 35248, 35276 (Aug. 3, 1983) (recognizing that the IB definition ''undoubtedly encompasses many business enterprises of variable size''); 47 FR at 18620 (the category of CTAs is ''too broad'' for a general determination regarding their small entity status).

[24] 44 U.S.C. 3501 *et seq.*

[25] *See* OMB Control No. 3038–0055, *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0055#* (last visited Nov. 30, 2018).

[26] The Commission endeavors to assess the expected costs and benefits of the Final Rule in quantitative terms where possible. Where estimation or quantification is not feasible, the Commission provides its discussion in qualitative terms. Given a general lack of relevant data, the Commission's assessment is generally provided in qualitative terms.

[27] The Commission notes that the consideration of costs and benefits below is based on the understanding that the markets function internationally, with many transactions involving United States firms taking place across international boundaries; with some commission registrants being organized outside of the United States; with some leading industry members typically conducting operations both within and outside the

Continued

The Commission anticipates that some Covered Persons may avail themselves of the exception in the Final Rule and not provide annual privacy notices. The Final Rule benefits these Covered Persons that are opting out of providing annual privacy notices by reducing their costs associated with sending such notices. Further, because no Covered Person is required to avail themselves of the exception in the Final Rule, as discussed above, the Commission believes that it is reasonable to conclude that only those Covered Persons that expect a net benefit from the Final Rule will stop providing annual privacy notices under the proposed exception.

The Commission recognizes that, as a result of the Final Rule, certain customers of Covered Persons may no longer receive privacy notices annually and therefore will not be made aware of the Covered Persons' policies and procedures as frequently. However, the scope of the exception is tailored such that customers of Covered Persons could only not receive an annual privacy notice to the extent that the Covered Person: (1) Provides nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of §§ 160.13, 160.14, 160.15 and any other exceptions adopted by the Commission pursuant to section 504(b) of the GLB Act; and (2) has not changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 160.6(a)(2) through (5) and § 160.6(a)(9) in the most recent privacy notice provided to such customer pursuant to part 160 of the Commission's regulations. Thus, the Final Rule may reduce confusion among customers by providing them with disclosures when they would be most relevant, *i.e.,* when disclosure policies change after the customer relationship begins and to the extent an institution shares sensitive personal information with third parties for marketing purposes.

In determining when to require the resumption of annual privacy notices following the loss of the exception in the Final Rule, the Commission endeavored to make its requirements consistent with existing timing requirements for privacy notices under current regulations, as discussed above, and to provide clarity to Covered Persons.[28] Specifically, in requiring the resumption of annual privacy notices within 100 days of the loss of the exception where a revised privacy notice is not required under § 160.8, the Commission has tried not to impose unnecessary burdens on Covered Persons while taking into account the potential impact on a Covered Person's customers of not receiving such notices in a timely manner. The Commission considered different requirements for the resumption of annual privacy notices in these circumstances (*e.g.,* requiring a notice before the change in the policy or practice causing the loss of the availability of the exception or immediately following such change, or within 60 or 90 days of such change). The Commission is providing the 100 day period because it believes the Final Rule to be consistent with the revisions of the GLB Act in the FAST Act and current regulations while allowing Covered Persons some flexibility in resuming annual privacy notices. This flexibility allows, for example, these notices to be included with quarterly statements to reduce any costs from resuming providing such notices. In providing timing requirements for the resumption of annual privacy notices where a revised notice is required under § 160.8, the Commission is clarifying the effect of such a revised notice on the requirement that a Covered Person provide an annual privacy notice and on the eligibility for the exception to this requirement. Specifically, the Commission is clarifying that a Covered Person must provide the notice currently required by § 160.8 and treat such notice as an initial privacy notice.

Section 15(a) Considerations. In light of the foregoing, the CFTC has evaluated the costs and benefits of the Final Rule pursuant to the five considerations identified in section 15(a) of the CEA as follows:

(1) Protection of Market Participants and the Public

The requirements of § 160.5 protect market participants by ensuring that customers of Covered Persons are informed about such Covered Persons' practices and policies with respect to nonpublic personal information and certain other information described in § 160.6. As discussed above, the Commission recognizes that, as a result of the Final Rule, some customers of Covered Persons may no longer receive privacy notices annually and therefore will not be made aware of the Covered Persons' policies and procedures as frequently. However, the scope of the exception is tailored such that customers of Covered Persons could only not receive an annual privacy notice to the extent that the Covered Person: (1) Provides nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of §§ 160.13, 160.14, 160.15 and any other exceptions adopted by the Commission pursuant to section 504(b) of the GLB Act; and (2) has not changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 160.6(a)(2) through (5) and § 160.6(a)(9) in the most recent privacy notice provided to such customer pursuant to part 160 of the Commission's regulations. Further, as discussed above, the Final Rule may reduce confusion among customers by providing them with disclosures when they would be most relevant. In addition, the Commission believes that the requirements for the resumption of annual privacy notices following the loss of the exception in the Final Rule will allow customers of Covered Persons to receive annual privacy notices in a timely manner while not causing Covered Persons to incur any additional costs.

(2) Efficiency, Competitiveness, and Financial Integrity of Markets

The Commission believes that the Final Rule may improve competition by reducing costs for Covered Persons that meet the requirements of the exception in § 160.5(d) to not deliver an annual privacy notice and elect to not deliver such notices. Specifically, the Commission expects that the Final Rule will likely result in fewer substantially similar annual privacy notices being delivered, which will reduce costs associated with producing and delivering such privacy notices. Further, to the extent that a Covered Person is no longer able to take advantage of the exception to providing annual privacy notices and is required to resume providing them, the Commission believes that a Covered Person will not incur any additional costs in doing so, as the Covered Person would simply need to resume sending annual privacy notices as currently required.

United States; and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion of costs and benefits below refers to the effects of this proposal on all activity subject to the proposed and amended regulations, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with or effect on United States commerce under CEA section 2(i). In particular, the Commission notes that some Covered Persons are located outside of the United States.

[28] In addition, as discussed above, the Commission notes that a Covered Person's obligation to resume providing annual privacy notices may be effectively a one-time burden absent additional changes to their policies and practices.

(3) Price Discovery

The Commission has not identified an impact on price discovery as a result of the Final Rule.

(4) Sound Risk Management

The Commission has not identified an impact on sound risk management as a result of the Final Rule.

(5) Other Public Interest Considerations

The Commission has not identified an impact on other public interest considerations as a result of the Final Rule.

Comments on Cost-Benefit Considerations. The Commission invited public comment on its cost-benefit considerations in the Proposal, including the Section 15(a) factors described above. The Commission received no such comments.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.[29] The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requested and did not receive any comments on whether the Proposal implicated any other specific public interest to be protected by the antitrust laws.

The Commission has considered this Final Rule to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requested and did not receive any comments on whether the Proposal was anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that this Final Rule is not anticompetitive and has no anticompetitive effects and received no comments on its determination, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA.

List of Subjects in 17 CFR Part 160

Brokers, Consumer protection, Privacy, Reporting and recordkeeping requirements.

[29] 7 U.S.C. 19(b).

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR chapter I as follows:

PART 160—PRIVACY OF CONSUMER FINANCIAL INFORMATION UNDER TITLE V OF THE GRAMM-LEACH-BLILEY ACT

■ 1. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 7b–2 and 12a(5); 15 U.S.C 6801, *et seq.,* and sec. 1093, Pub. L. 111–203, 124 Stat. 1376.

■ 2. In § 160.5, revise the first sentence of paragraph (a)(1) and add paragraph (d) to read as follows:

§ 160.5 Annual privacy notice to customers required.

(a)(1) * * * Except as provided by paragraph (d) of this section, you must provide a clear and conspicuous notice to customers that accurately reflects your privacy policies and practices not less than annually during the life of the customer relationship. * * *

* * * * *

(d) *Exception to annual privacy notice requirement.* (1) You are not required to deliver an annual privacy notice if you:

(i) Provide nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of §§ 160.13, 160.14, and 160.15 and any other exceptions adopted by the Commission pursuant to section 504(b) of the GLB Act; and

(ii) Have not changed your policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 160.6(a)(2) through (5) and § 160.6(a)(9) in the most recent privacy notice sent to the customer pursuant to this part.

(2) *Delivery of annual privacy notice after you no longer meet requirements for exception.* If you have been excepted from delivering an annual privacy notice pursuant to paragraph (d)(1) of this section and change your policies or practices in such a way that you no longer meet the requirements for that exception, you must comply with paragraph (d)(2)(i) or (ii) of this section, as applicable.

(i) *Changes preceded by a revised privacy notice.* If you no longer meet the requirements of paragraph (d)(1) of this section because you change your policies or practices in such a way that § 160.8 of this part requires you to provide a revised privacy notice, you must provide an annual privacy notice in accordance with the timing requirements in paragraph (a) of this section, treating the revised privacy notice as an initial privacy notice.

(ii) *Changes not preceded by a revised privacy notice.* If you no longer meet the requirements of paragraph (d)(1) of this section because you change your policies or practices in such a way that § 160.8 of this part does not require you to provide a revised privacy notice, you must provide an annual privacy notice within 100 days of the change in your policies or practices that causes you to no longer meet the requirements of paragraph (d)(1) of this section.

Issued in Washington, DC, on April 19, 2019, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Appendix to Privacy of Consumer Financial Information—Amendment To Conform Regulations to the Fixing America's Surface Transportation Act—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2019–08253 Filed 4–24–19; 8:45 am]

BILLING CODE 6351–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2018–0159; FRL–9991–33]

RIN 2070–AK45

Restrictions on Discontinued Uses of Asbestos; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is promulgating a rule to ensure that any discontinued uses of asbestos cannot re-enter the marketplace without EPA review, closing a loophole in the regulatory regime for asbestos.

DATES: This final rule is effective June 24, 2019.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0159, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Robert Courtnage, National Program Chemicals Division (Mail Code 7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1081; email address: *courtnage.robert@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION: This restrictive rule is called a significant new use rule (SNUR) for asbestos, as the term asbestos is defined under the Asbestos Hazard Emergency Response Act. The restricted significant new uses of asbestos (including as part of an article) is manufacturing (including importing) or processing for uses that are neither ongoing nor already prohibited under TSCA. The Agency has found no information indicating that the following uses are ongoing, and therefore, the following uses are subject to this SNUR and cannot return to the marketplace without EPA review: Adhesives, sealants, and roof and non-roof coatings; arc chutes; beater-add gaskets; cement products; extruded sealant tape and other tape; filler for acetylene cylinders; friction materials (with certain exceptions identified in Table 1); high-grade electrical paper; millboard; missile liner; packings; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; woven products; any other building material; and any other use of asbestos that is neither ongoing nor already prohibited under TSCA. This action prohibits these discontinued uses of asbestos from restarting without EPA having an opportunity to evaluate each intended use (*i.e.,* significant new use) for potential risks to health and the environment and take any necessary regulatory action, which may include a prohibition. This SNUR does not provide a means by which prohibited uses under the 1989 partial ban under TSCA section 6 could return to the marketplace. This SNUR keeps all prior asbestos prohibitions in place and would not amend them in any way. EPA is focused on protecting the public from exposure to asbestos, and as such persons subject to the SNUR may not undertake any of these activities; they are required to notify EPA at least 90 days before commencing any manufacturing (including importing) or processing of asbestos (including as part of an article) for a significant new use. The required notification initiates EPA's evaluation of the conditions of use associated with the intended use. Manufacturing (including importing) and processing (including as part of an article) for the significant new use may not commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute in commerce asbestos as it is defined by TSCA Title II, section 202 (15 U.S.C. 2642) (including as part of an article). The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Construction (NAICS code 23);
- Manufacturing (NAICS codes 31—33);
- Wholesale Trade (NAICS code 42); and
- Transportation (NAICS code 48).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA (15 U.S.C. 2601 *et seq.*). Persons who import or process any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127 (see also 19 CFR 127.28). Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

In addition, asbestos, as defined in this rule, is already subject to TSCA section 6(a) (40 CFR part 763, subparts G and I) rules that trigger the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b); see also 40 CFR 721.20). Any person who exports or intends to export asbestos must comply with the export notification requirements in 40 CFR part 707, subpart D; however, although EPA makes inapplicable the exemption at 40 CFR 721.45(f) for persons who import or process any asbestos as part of an article in a category listed in Table 1, the Agency is not requiring export notification for articles containing asbestos, as further explained in Unit III.B. of this notice.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2) (see Unit IV.). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA prohibits the manufacturing (including importing) or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). Those actions could include a prohibition on a use of that chemical substance. As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What action is the Agency taking?

EPA is promulgating a final SNUR for asbestos, using the definition in TSCA Title II, section 202, which defines asbestos as the ''asbestiform varieties of six fiber types—chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.'' The significant new use of asbestos (including as part of an article) is manufacturing (including importing) or processing for uses that are neither ongoing nor already prohibited under TSCA. The Agency found no information indicating that the following uses are ongoing, and

therefore, the following uses are subject to this SNUR: Adhesives, sealants, and roof and non-roof coatings; arc chutes; beater-add gaskets; cement products; extruded sealant tape and other tape; filler for acetylene cylinders; friction materials (with certain exceptions identified in Table 1); high-grade electrical paper; millboard; missile liner; packings; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; woven products; any other building material; and any other use of asbestos that is neither ongoing nor already prohibited under TSCA.

Table 1 below presents the significant new uses of asbestos (including as part of an article) subject to this rule and lists product categories of asbestos uses that are no longer ongoing (*i.e.,* discontinued uses) in the United States that this SNUR will prohibit from restarting under TSCA without EPA's prior notice, review, and, as necessary, regulation by EPA. Unless otherwise noted, the product category descriptions are based on those presented in the *Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products* for the 1989 final rule (Ref. 1).

TABLE 1—RESTRICTED PRODUCT CATEGORIES OF SIGNIFICANT NEW USES OF ASBESTOS

Product category	Description of the product category
Adhesives, Sealants, and Roof and Non-Roof Coatings.	The automobile industry historically used asbestos in a wide variety of adhesive, sealant, and coating applications. The aerospace industry used asbestos in extremely specialized applications such as firewall sealants and epoxy adhesives. Non-roof coatings were used to prevent corrosion (*e.g.,* as vehicle undercoatings and underground pipe coatings). Roof coatings were used to repair and patch roofs, seal around projections such as chimneys and vent pipes, and bond horizontal and vertical surfaces.
Arc Chutes	Ceramic arc chutes containing asbestos were used to guide electric arcs in motor starter units in electric generating plants.
Beater-Add Gaskets	Asbestos fibers were incorporated within various elastomeric binders and other fillers to form the beater-add paper. These products were used extensively for internal combustion applications and for the sealing component of spiral wound gaskets. Gaskets were used to seal one compartment of a device from another in non-dynamic applications such as engine and exhaust manifolds.
Cement Products *	Includes asbestos cement product categories in the 1989 Regulatory Impact Assessment: Asbestos-Cement Pipe and Fittings, Asbestos-Cement Flat Sheet, Corrugated Asbestos-Cement Sheet, and Asbestos-Cement Shingles.
Extruded Sealant Tape and Other Tape.	Sealant tape was made from a semi-liquid mixture of butyl rubber and asbestos. On exposure to air, the sealant solidified forming a rubber tape about an inch wide and an eighth of an inch thick. The tape acted as a gasket for sealing building windows, automotive windshields, and mobile home windows. It was also used in the manufacture of parts for the aerospace industry and in the manufacture of insulated glass.
Filler for Acetylene Cylinders	Asbestos was used to produce a sponge-like filler, which held the liquefied acetylene gas (acetone) in suspension in the steel cylinder and puled the acetone up through the tank as the gas was released through the oxyacetylene torch. The torch was used to weld or cut metal and sometimes used as an illuminant gas. The filler also acted as an insulator that offered fire protection in case the oxidation of the acetylene became uncontrollable.
Friction Materials (except brake blocks used in oil drilling equipment; aftermarket automotive brakes/linings; and other vehicle friction products).	Friction materials were used as braking and gear-changing (clutch) components in a variety of industrial and commercial machinery. Applications included agricultural equipment such as combines, mining and oil-well-drilling equipment, construction equipment such as cranes and hoists, heavy equipment used in various manufacturing industries (*e.g.,* machine tools and presses), military equipment, marine engine transmissions, elevators, chain saws, and consumer appliances such as lawn mowers, washing machines, and vacuum cleaners.
High-Grade Electrical Paper	The major use of asbestos electrical paper was insulation for high temperature, low voltage applications such as in motors, generators, transformers, switch gears, and other heavy electrical apparatuses.
Millboard	Asbestos millboard was essentially a heavy cardboard product that was used for gasketing, insulation, fireproofing, and resistance against corrosion and rot. Millboard was used in many industrial applications to include linings in boilers, kilns, and foundries; insulation in glass tank crowns, melters, refiners, and sidewalls in the glass industry; linings for troughs and covers in the aluminum, marine, and aircraft industries; and thermal protection in circuit breakers in the electrical industry. In addition, thin millboard was inserted between metal to produce gaskets. Commercial applications for millboard included fireproof linings for safes, dry-cleaning machines, and incinerators.
Missile Liner	A missile liner was an asbestos and rubber compound used to insulate the outer casing of the rocket from the intense heat generated in the rocket motor while the rocket fuel was burned. Rockets and rocket boosters were used to propel a number of objects including military weapons and the space shuttle.
Packings	Asbestos packings were dynamic or mechanical (static packings are gaskets) and used to seal fluids in devices where motion was necessary. The design of a packing is to control the amount of leakage of fluid at shafts, rods or valve systems and other functional parts or equipment requiring containment of liquids or gases. Asbestos packings were used in rotary, centrifugal, and reciprocating pumps, valves, expansion joints, soot blowers, and many other types of mechanical equipment.
Pipeline Wrap	Pipeline wrap was an asbestos felt product primarily used by the oil and gas industry for coating its pipelines. Asbestos pipeline wrap was also used in the coal tar enamel method of coating pipes, some above-ground applications (such as for special piping in cooling towers) and was also used by the chemical industry for underground hot water and steam piping.
Reinforced Plastics	Asbestos-reinforced plastics were used for electro-mechanical parts in the automotive and appliance industries and as high-performance plastics for the aerospace industry. Asbestos-reinforced plastic was typically a mixture of some type of plastic resin (usually phenolic or epoxy), a general filler (often chalk or limestone), and raw asbestos fiber.
Roofing Felt	Asbestos roofing felt was single or multi-layered grade and used for built-up roofing. Asbestos was used in roofing felts because of its dimensional stability and resistance to rot, fire, and heat.

TABLE 1—RESTRICTED PRODUCT CATEGORIES OF SIGNIFICANT NEW USES OF ASBESTOS—Continued

Product category	Description of the product category
Separators in Fuel Cells and Batteries.	In very specialized aerospace applications, asbestos functioned as an insulator and separator between the negative and positive terminals of a fuel cell/battery.
Vinyl-Asbestos Floor Tile	Vinyl-asbestos floor tile was used in commercial, residential, and institutional buildings in heavy traffic areas such as supermarkets, department stores, commercial plants, kitchens, and ''pivot points''—entry ways and areas around elevators
Woven Products*	Includes Protective Clothing and Asbestos Textiles from the 1989 RIA.
Any Other Building Material	Examples include insulation, plasters, mastics, textured paints (*e.g.,* simulates stucco), and block filler paints (*e.g.,* for coating masonry).
Any use of asbestos not otherwise identified.	Except those uses prohibited under § 763.165 (*i.e.,* Corrugated Paper, Rollboard, Commercial Paper Specialty Paper, Flooring Felt and New Uses (the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989)) and uses of imported chrysotile (including as part of an article) that are currently ongoing in the United States (*i.e.,* diaphragms; sheet gaskets; oilfield brake blocks; aftermarket automotive brakes/linings; other vehicle friction products; and other gaskets).

*Not a product category described in the same terms in the Regulatory Impact Analysis (Ref. 1); this broader product category is used generally to describe a number of specific product categories identified during the TSCA section 6 risk evaluation process.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114–182, 130 Stat. 448) amended TSCA in June 2016. As amended, TSCA includes statutory requirements related to the risk evaluations of existing chemicals under their conditions of use. In December of 2016 (81 FR 91927, December 19, 2019) (FRL–9956–47), EPA designated asbestos as one of the first 10 chemical substances subject to the Agency's chemical risk evaluation rule, pursuant to TSCA section 6(b)(2)(A) (15 U.S.C. 2605(b)(2)(A)).

EPA is separately conducting a risk evaluation of asbestos under its conditions of use, pursuant to TSCA section 6(b)(4)(A). Through scoping and subsequent research for the asbestos risk evaluation, EPA identified several conditions of use of asbestos to include in the risk evaluation. However, through extensive research, review of public comments, and stakeholder engagement, the conditions of use of asbestos have been further refined since publication of the proposed Asbestos SNUR (83 FR 26922, June 11, 2018) (FRL–9978–76), and *Problem Formulation of the Risk Evaluation for Asbestos* (Ref. 2) in June 2018. The conditions of use of asbestos currently undergoing risk evaluation include: Imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; and several imported chrysotile asbestos-containing materials, including sheet gaskets for use in chemical production (*e.g.,* titanium dioxide production), brake blocks used in oil drilling equipment, aftermarket automotive brakes/linings and other vehicle friction products, and other gaskets. Cement products, woven products, and packings have been removed from the scope of the risk evaluation since publication of the problem formulation document because no information was found to confirm they are conditions of use. Because additional EPA research indicates that cement products, woven products, and packings are not ongoing uses, this significant new use rule includes them as significant new uses. This final SNUR does not affect those uses that EPA believes are currently ongoing in the United States; again, those uses are being evaluated in the context of EPA's asbestos risk evaluation.

EPA requested public comment on the proposed SNUR for information regarding any ongoing uses not identified by the Agency and additional uses no longer ongoing (83 FR 26922, June 11, 2018) (FRL–9978–76). The Agency did not receive any comments providing additional information regarding the ongoing uses or discontinued uses of asbestos. EPA did receive many comments (too numerous to cite individually) stating that the Agency should not allow otherwise prohibited asbestos uses to return to the marketplace. EPA's approach is consistent with these comments, and this rulemaking does not bring previously prohibited uses back to market. This SNUR regulates uses of asbestos that are no longer ongoing (*i.e.,* discontinued uses) in the United States but that are not currently prohibited from restarting under TSCA (*i.e.,* not subject to the 1989 partial ban under TSCA section 6). In the absence of this SNUR, manufacturing, importing, or processing of asbestos (including as part of an article) for the significant new uses identified in Table 1 may begin at any time and without prior notice to and oversight by EPA. EPA is committed to protecting the public from asbestos risks. As such, EPA will ensure through this final rule that no former uses of asbestos can be reintroduced into commerce in the U.S. without prior notice, review, and, as necessary, regulation by EPA.

As explained in greater detail in the *Response to Comments* document (Ref. 3), a significant new use rule can be promulgated to regulate new chemicals or existing chemicals. For existing chemicals, such as asbestos, a SNUR can be used to ensure that no company will be able to manufacture, import, or process the chemical for uses the Agency identifies as significant new uses without prior notification to EPA and not before EPA has conducted a review of the notice, made an appropriate determination on the notice based on information available to EPA about the risk to health and the environment, and taken such regulatory actions as are required in association with that determination. This final SNUR requires persons who intend to manufacture (including import) or process any form of asbestos as defined under Title II of TSCA (including as part of an article) for a significant new use listed in Table 1, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacturing (including importing) or processing. Furthermore, this rule precludes the commencement of such manufacturing (including importing) or processing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.

EPA intends that the provisions of this rule be severable. In the event that any individual provision or part of this rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

D. Why is the Agency taking this action?

This final SNUR will require timely advance notice to EPA of any future manufacturing (including importing) or processing of asbestos (including as part of an article) for the designated significant new uses that may produce changes in human and environmental exposures and to allow EPA to make an appropriate determination (relevant to the risks associated with such manufacturing (including importing), processing, and use) prior to the commencement of such manufacturing (including importing) or processing. This action is necessary to ensure that manufacturing (including importing) or processing for the significant new use cannot proceed until EPA has responded to the circumstances by taking the required actions under TSCA sections 5(e) or 5(f) in the event that EPA determines any of the following: (1) That the significant new use presents an unreasonable risk to health or the environment under the conditions of use (without consideration of costs or other non-risk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) that, in the absence of sufficient information, the manufacturing (including importing), processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable risk (without consideration of costs or other non-risk factors, and including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA); or (4) that there is substantial production and sufficient potential for environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)).

There is a strong causal association between asbestos exposure and lung cancer and mesotheliomas (tumors arising from the thin membranes that line the chest (thoracic) and abdominal cavities and surround internal organs) (Ref. 4; Ref. 5 Ref. 6; Ref. 7; Ref. 8; Ref. 9). In addition, other cancers, as well as non-cancer effects, such as respiratory and immune effects, have been associated with asbestos exposure (Ref. 10).

Agency research conducted in support of the TSCA risk evaluation of asbestos revealed that the use of asbestos has declined dramatically in the United States since the 1970s when asbestos use was at its peak. Nevertheless, EPA is concerned about the potential for adverse health effects of asbestos and believes this action will prevent former uses of asbestos from being reintroduced into commerce without the EPA being aware and having the opportunity to review and, as necessary, restrict those uses. EPA is taking action in this final rule to prohibit manufacturing (including importing) or processing for a significant new use of asbestos (including as part of an article) identified in Table 1 in the United States without prior notice, review, and, as necessary, regulation by EPA. The rationale and objectives for this final SNUR are explained in additional detail in Unit III. of the proposed rule (83 FR 26922, June 11, 2018) (FRL–9978–76).

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of asbestos, as defined in this rule. This Economic Analysis (Ref. 11), which is available in the docket, is discussed in Unit IX. and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be approximately $23,000 per SNUN submission for large business submitters and about $10,000 for small business submitters. Asbestos is already subject to TSCA section 6(a) rules (40 CFR part 763, subparts G and I) that trigger the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b); see also 40 CFR 721.20), and the Agency is not requiring export notifications for articles containing asbestos. Articles are generally excluded from the TSCA section 12(b) export notification requirements and the Agency is not lifting the article exemption for 12(b) export notification for asbestos articles for the reasons discussed in Unit III.B. Therefore, EPA assumes no additional costs under TSCA section 12(b) for this rule.

The rule may also affect firms that plan to import or process articles that may be subject to the SNUR. Although there are no specific requirements in the rule for these firms, they may choose to undertake some activity to assure themselves that they are not undertaking a significant new use. In the accompanying Economic Analysis for this final SNUR (Ref. 11), example steps (and their respective costs) that an importer or processor might take to identify asbestos in articles are provided. These steps can include gathering information through agreements with suppliers, declarations through databases or surveys, or use of a third-party certification system. Additionally, importers may require suppliers to provide certificates of testing analysis of the products or perform their own laboratory testing of certain articles. EPA is unable to predict, however, what, if any, particular steps an importer might take; thus, potential total costs were not estimated.

II. Chemical Substance Subject to This Final Rule

A. What chemicals are included in the final SNUR?

This SNUR applies to asbestos, using the definition in TSCA Title II, section 202, which defines asbestos as the ''asbestiform varieties of six fiber types—chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.'' This SNUR applies to the manufacturing (including importing) or processing of asbestos (including as part of an article) for uses that are neither ongoing nor already prohibited under TSCA. EPA found no information indicating that the following uses are ongoing, and therefore, the following uses are subject to this final SNUR: Adhesives, sealants, and roof and non-roof coatings; arc chutes; beater-add gaskets; cement products; extruded sealant tape and other tape; filler for acetylene cylinders; friction materials (with certain exceptions identified in Table 1); high-grade electrical paper; millboard; missile liner; packings; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; woven products; any other building material; and any other use of asbestos that is neither ongoing nor already prohibited under TSCA. This action enables the Agency to protect public health because these significant new uses are not permitted to commence until EPA conducts a review and evaluates risks, and, as necessary, restricts the use(s).

Under this final SNUR, the exemption at 40 CFR 721.45(f) would not apply to persons who import or process asbestos as part of an article (which includes as a component of an article) because there is reasonable potential for exposure to asbestos if the substance is incorporated into articles and then imported or processed. Asbestos-containing articles subject to this SNUR are listed in Table 1.

B. What are the production volumes and uses of asbestos?

Asbestos has not been mined or otherwise produced in the United States since 2002; therefore, any new raw bulk asbestos used in the United States is imported. According to the U.S. Geological Survey (USGS), approximately 750 metric tons of raw bulk asbestos was imported into the United States in 2018 (Ref. 12). Chrysotile is the only form of raw bulk asbestos currently imported, and the chlor-alkali industry is the only known importer (Ref. 12). EPA did not identify any domestic entity that uses raw bulk asbestos other than the chlor-alkali industry, which uses chrysotile asbestos to fabricate diaphragms for use in chlorine and sodium hydroxide production.

In an effort to identify national import volumes and conditions of use for the asbestos risk evaluation being conducted under TSCA section 6(b)(4)(A), EPA searched a number of available data sources including EPA's Chemical Data Reporting (CDR) database, USGS's Mineral Commodities Summary and the Minerals Yearbook, the U.S. International Trade Commission's Dataweb, the U.S. Customs and Border Protection's Automated Commercial Environment (ACE) system, and the *Use and Market Profile for Asbestos* (Ref. 13). Based on this research, EPA published a preliminary list of information and sources related to asbestos conditions of use prior to a February 2017 public meeting on the scoping efforts for the risk evaluation convened to solicit public comment (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos,* Ref. 14). EPA also convened meetings with companies, associated industry groups, chemical users, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA.

During the public comment period for the *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos* (Ref. 14), one company identified the use of asbestos-containing gaskets, which are imported, for use during the production of titanium dioxide. During stakeholder discussions another company confirmed importing and distributing brake blocks for use in oil drilling equipment by the oil industry. EPA believes that aftermarket automotive brakes/linings and other vehicle friction products, and other gaskets containing asbestos are also imported, as reported by USGS (Ref. 15) and also appear in data from ACE; however, the volume of products and the quantity of asbestos within imported products is not fully known. These conditions of use along with the others listed in Table 3 will be subject to the TSCA section 6 risk evaluation.

On June 22, 2017, EPA published the *Scope of the Risk Evaluation for Asbestos* (Ref. 10), which was further refined by the June 2018, *Problem Formulation of the Risk Evaluation for Asbestos* (Ref. 2) issued in conjunction with the June 11, 2018 proposed Asbestos SNUR (83 FR 26922, June 11, 2018) (FRL–9978–76). Each of these three actions provided 60-day comment periods and opportunity for the public and private sector to identify conditions of use of asbestos in the United States. The Agency did not receive additional information from the public comments during the comment period regarding ongoing or discontinued uses of asbestos.

C. What are the potential health effects of asbestos?

Asbestos was listed as a known human carcinogen in the National Toxicology Program's *First Annual Report on Carcinogens* in 1980 (Ref. 16). In 1988, EPA assessed the health hazards and effects caused by exposure to asbestos under the Integrated Risk Information System (IRIS) program and determined that asbestos exposure can lead to lung cancer and mesotheliomas (tumors arising from the thin membranes that line internal organs) (Ref. 5). There is causal association between asbestos and lung cancer and mesotheliomas (Ref. 4; Ref. 6; Ref. 7). EPA also noted in the *Scope of the Risk Evaluation for Asbestos* (Ref. 10) that there is a causal association between exposure to asbestos and cancer of the larynx and cancer of the ovary (Ref. 7). There is also suggestive evidence of a positive association between asbestos and cancer of the pharynx (Ref. 7; Ref. 17), stomach (Ref. 6; Ref. 7), and colorectum (Ref. 4; Ref. 6; Ref. 7; Ref. 17; Ref. 18; Ref. 19). All types of asbestos fibers have been reported to cause mesothelioma (Ref. 7).

Increases in lung cancer mortality have been reported in both workers and residents exposed to various asbestos fiber types as well as fiber mixtures (Ref. 7). There is evidence in *in-vitro,* animal, and human studies that asbestos is genotoxic, meaning asbestos can damage an organism's genetic material (Ref. 6). There is also evidence that asbestos exposure is associated with adverse respiratory system effects, such as asbestosis and immunotoxicity (Ref. 6; Ref. 10).

D. What are the potential routes and sources of exposure to asbestos?

The greatest risk of exposure to asbestos occurs when the substance is in a friable state, meaning the fibers can be crumbled, pulverized, or reduced to a powder under hand pressure (Ref. 6). During use and over time, non-friable asbestos has the potential to become friable (Ref. 6). For example, testing has shown that non-friable asbestos-containing material can become friable during use such as cutting, crumbling, and tearing, and as a result of such use, asbestos fibers can be released into the air (Ref. 20). Similarly, non-friable asbestos-containing building materials can release fibers if disturbed during building repair or demolition (Ref. 21). Exposures to workers, consumers and the general population, as well as environmental receptors, may occur from industrial releases and use of asbestos-containing products. Based on EPA's research conducted during the early stages of the TSCA risk evaluation, most of the ongoing uses of asbestos pertain to industrial and commercial uses (Ref. 10).

The primary exposure route for asbestos is inhalation. Asbestos fibers can be released into the air during processing of raw bulk asbestos and asbestos-containing products. Weathering and the disturbance and/or degradation of asbestos-containing products can also cause asbestos fibers to be suspended in air (Ref. 6). Fibers can then enter the lungs through inhalation. Exposures to asbestos can potentially occur via oral and dermal routes; however, EPA anticipates that the most likely exposure route is inhalation.

III. SNUR Rationale and Objectives

A. Rationale

As discussed in Unit II. and Unit III. of the proposed rule (83 FR 26922, June 11, 2018) (FRL–9978–76), EPA is concerned about the potential for adverse health effects of asbestos based on established sound scientific data indicating that asbestos is a known human carcinogen. Asbestos was listed as a human carcinogen in the National Toxicology Program's *First Annual Report on Carcinogens* in 1980 (Ref. 16).

Asbestos, in particular chrysotile asbestos, has several useful properties, including low electrical conductivity while maintaining high tensile strength, high friction coefficient, and high resistance to heat (Ref. 19). These properties made asbestos ideal for use in friction materials (*e.g.,* brakes), insulation (*e.g.,* sound, heat, and electrical), and building materials (*e.g.,*

cement pipes, roofing compounds, flooring) over the past century. However, the use of asbestos has declined dramatically due to health concerns and consumer preference (Ref. 22), which has led to the elimination of some exposure scenarios associated with such uses. According to USGS, in 1973, national annual consumption, including manufacturing/importing and processing, of raw bulk asbestos peaked around 800,000 metric tons and has since fallen approximately 99 percent to between 300 and 800 metric tons in recent years (Ref. 12). Today, most manufactured products that historically contained asbestos in the United States are now asbestos-free (Ref. 22).

In 1989, EPA published a final rule *Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions* (54 FR 29460, July 12, 1989) (FRL–3476–2), which was intended ''to prohibit, at staged intervals, the future manufacture, importation, processing and distribution in commerce of asbestos in almost all products, as identified in the rule . . .'' and to ''reduce the unreasonable risks presented to human health by exposure to asbestos during activities involving these products.'' The 1989 final rule applied to the asbestos product categories identified in the *Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products* (Ref. 1), which was conducted in support of the rule. However, the ban against most of the asbestos product categories was partially vacated and remanded to EPA by the Fifth Circuit Court of Appeals in 1991. In addition to the asbestos products that remain banned after the court ruling, which are identified in Table 2 below, any new use of asbestos was also banned. This prohibition on any new uses of asbestos is for uses initiated *for the first time* after August 25, 1989. The purpose of this SNUR is to address the uses of asbestos that began prior to August 25, 1989, for which manufacturing (including importing) and processing are no longer ongoing in the United States but are not prohibited under the 1989 partial ban under TSCA section 6.

TABLE 2—ASBESTOS CONTAINING PRODUCT CATEGORIES BANNED UNDER TSCA SECTION 6

Product category	Definition (40 CFR 763.163)
Corrugated Paper	Corrugated paper means an asbestos-containing product made of corrugated paper, which is often cemented to a flat backing, may be laminated with foils or other materials, and has a corrugated surface. Major applications of asbestos corrugated paper include: Thermal insulation for pipe coverings; block insulation; panel insulation in elevators; insulation in appliances; and insulation in low-pressure steam, hot water, and process lines.
Rollboard	Rollboard means an asbestos-containing product made of paper that is produced in a continuous sheet, is flexible, and is rolled to achieve a desired thickness. Asbestos rollboard consists of two sheets of asbestos paper laminated together. Major applications of this product include: Office partitioning; garage paneling; linings for stoves and electric switch boxes; and fire-proofing agent for security boxes, safes, and files.
Commercial Paper	Commercial paper means an asbestos-containing product that is made of paper intended for use as general insulation paper or muffler paper. Major applications of commercial papers are insulation against fire, heat transfer, and corrosion in circumstances that require a thin, but durable, barrier.
Specialty Paper	Specialty paper means an asbestos-containing product that is made of paper intended for use as filters for beverages or other fluids or as paper fill for cooling towers. Cooling tower fill consists of asbestos paper that is used as a cooling agent for liquids from industrial processes and air conditioning systems.
Flooring Felt	Flooring felt means an asbestos-containing product that is made of paper felt intended for use as an underlayer for floor coverings, or to be bonded to the underside of vinyl sheet flooring.
New Uses *	The commercial uses of asbestos not identified in § 763.165 the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989.

* A ''new use'' as defined in 40 CFR 763.163 is distinct from a significant new use per TSCA section 5(a)(2), which is explained for the purposes of this final rule in Table 1.

After the court's ruling in *Corrosion Proof Fittings* v. *EPA,* 947 F.2d 1201 (5th Cir. 1991), only the specific asbestos products identified in Table 2 and new uses of asbestos initiated for the first time after August 25, 1989, remained banned under TSCA. This SNUR keeps these prohibitions in place and would not amend them in any way. In other words, this SNUR does not provide a means by which these prohibited uses under the 1989 partial ban under TSCA section 6 could return to the marketplace.

A significant new use of asbestos includes all uses that were initiated on or before August 25, 1989 (and were not covered by the 1989 partial ban under TSCA section 6) for which manufacturing (including importing) and processing are no longer ongoing in the United States. This SNUR is designed to complement the existing prohibitions on asbestos and does not alter or displace those prohibitions.

As part of the current asbestos risk evaluation process, the Agency identified conditions of use to be considered under the TSCA risk evaluation. In the proposed Asbestos SNUR (83 FR 26922, June 11, 2018) (FRL–9978–76) and the *Problem Formulation of the Risk Evaluation for Asbestos* (Ref. 2), the Agency identified the following conditions of use to be considered under the TSCA section 6 risk evaluation: Imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production and several imported chrysotile asbestos-containing materials including sheet gaskets for use in chemical production (*e.g.,* titanium dioxide chemical production), brake blocks for use in oil drilling, aftermarket automotive brakes/linings and other vehicle friction products, other gaskets and packing, cement products, and woven products. However, since the problem formulation document and proposed SNUR were published in June 2018, EPA has further refined the conditions of use of asbestos for the TSCA section 6 risk evaluation. Three uses of asbestos—cement products, packings, and woven products—were believed to be possibly ongoing based on import data reported in USGS's 2016 Mineral Yearbook (Ref. 16). EPA further investigated the import data and determined that there is no evidence to support that asbestos-containing cement products, packings, and woven products are ongoing uses of asbestos, and therefore, these three uses are subject to this final rulemaking.

In an effort to obtain confirmation that asbestos-containing cement products are imported into the U.S., EPA contacted the last known foreign supplier to North America. After contacting them, the supplier informed the Agency that they do not export asbestos-containing cement to the United States (Ref. 23). The Agency also discussed the use of asbestos cement pipe in the U.S. with the trade organization American Water Works, who provided a written statement that, to their knowledge, asbestos cement pipe is no longer an ongoing use (Ref. 24).

Upon further review of import data, EPA determined that packings and ''woven and knitted fabrics,'' which are reported in USGS's 2016 Minerals Yearbook (Ref. 16) under Harmonized Tariff Schedule (HTS) codes 6812.99.0020 and 6812.99.0004 respectively, were misreported. EPA also determined that the import data suggesting that imported packings contain asbestos pertained to gaskets, not packings. The Agency contacted a potential exporter of asbestos-containing woven products, but the company stated that they do not have customers in the United States (Ref. 25). EPA has included woven products in this SNUR because there is no evidence of ongoing use of woven products.

Based on further outreach and investigation since June 2018, the refined conditions of use of asbestos currently undergoing risk evaluation include: Imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; and several imported chrysotile asbestos-containing materials, including sheet gaskets for use in chemical products (*e.g.,* titanium dioxide chemical production), brake blocks used in oil drilling equipment, aftermarket automotive brakes/linings and other vehicle friction products, and other gaskets. Cement products, packings, and woven products have been removed from the risk evaluation since publication of the problem formulation document because no information was found to confirm they are conditions of use. Because additional EPA research indicates that cement products, woven products and packings are not ongoing uses, this SNUR includes them as significant new uses. This SNUR does not identify as significant new uses those uses that EPA believes are currently ongoing in the United States. The conditions of use of asbestos that are undergoing risk evaluation are specific to the chrysotile form only, which is the only known form of asbestos that is still manufactured or imported into the United States. Therefore, manufacturing, importing, mining, or processing crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite for a significant new use of asbestos (including as part of an article) or any use whatsoever requires a significant new use notification to EPA.

In the proposed SNUR, the Agency requested comment on the ongoing uses of asbestos as well as uses that are no longer ongoing (83 FR 26922, June 11, 2018) (FRL–9978–76). EPA received several comments suggesting that the SNUR be revised to include all product uses of asbestos that are no longer ongoing, and some commenters suggested targeting all uses of asbestos except ongoing uses currently under consideration for the asbestos TSCA section 6 risk evaluation (EPA–HQ–OPPT–2018–0159–1269; EPA–HQ–OPPT–2018–0159–1271; EPA–HQ–OPPT–2018–0159–5755; EPA–HQ–OPPT–2018–0159–5886). Considering that asbestos has been used in thousands of applications, EPA recognizes the public's comments on the significant new use rule as originally proposed and whether it covered all uses of asbestos that are no longer ongoing in the United States. The Agency's intent in this final SNUR is to cover all uses of asbestos that are neither ongoing in the United States nor already banned under TSCA. In response to public comment since proposal, the Agency is revising the regulatory text to add another broad use category to ensure all other uses of asbestos that are no longer ongoing and not already prohibited under TSCA are captured in this rulemaking. EPA is explicitly excluding from this rulemaking uses of asbestos that are already prohibited under TSCA through the 1989 partial ban under TSCA section 6 or are currently ongoing. Ongoing uses identified by EPA as conditions of use under consideration for the TSCA section 6 risk evaluation (*i.e.,* imported chrysotile for the fabrication of asbestos diaphragms and the following imported chrysotile products: Sheet gaskets, oilfield brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets) are not significant new uses of asbestos and therefore would not require a significant new use notice submission to the Agency.

As explained in the proposed rule (83 FR 26922, June 11, 2018) (FRL–9978–76), as part of the information gathering activity associated with the current asbestos TSCA section 6 risk evaluation, the Agency researched market availability for the asbestos product categories subject to the 1989 TSCA section 6 ban that was later partially vacated and remanded to EPA. In addition to the asbestos product categories that EPA identified in the proposed SNUR where manufacturing (including importing) and processing for the use is no longer ongoing, the Agency has determined that the product category ''friction materials'' as defined in Table 1 (and with the exceptions noted in Table 1) is also a significant new use of asbestos. While this product category was in the 1989 Regulatory Impacts Analysis (Ref. 1), it was not included in the proposed SNUR because the broad category definition could be viewed as contradictory to uses not subject to the rule—brake blocks in particular. However, in response to public comments, the Agency is including friction materials as defined in Table 1 within the significant new use for asbestos, to encompass all uses that the Agency has determined to be neither ongoing in the United States nor already prohibited under TSCA. The Agency believes it is appropriate to include the product category of ''friction materials'' in the scope of this SNUR and doing so will not create confusion or potentially overlapping definitions.

Table 3 represents the conditions of use for asbestos which are undergoing risk evaluation under TSCA section 6. These uses are ongoing uses that are not covered under the 1989 partial ban under TSCA section 6 nor in this final SNUR. All of the remaining ongoing uses of asbestos are solely for chrysotile asbestos. Ongoing uses identified by EPA as conditions of use under consideration for the TSCA section 6 risk evaluation are not significant new uses of asbestos and therefore are not subject to this rulemaking and would not require a significant new use notice submission to the Agency.

TABLE 3—CONDITIONS OF USE OF ASBESTOS THAT ARE NOT SIGNIFICANT NEW USES OF ASBESTOS

Product category	Example
Asbestos Diaphragms	Chlor-alkali Industry.
Sheet Gaskets	Chemical Manufacturing Industry.
Oilfield Brake Blocks	Oil Industry.
Aftermarket Automotive Brakes/Linings.	Automotive Industry.
Other Vehicle Friction Products.	Automotive Industry.
Other Gaskets	Non-automotive Vehicle Industry.

As discussed in Unit 1.C., EPA is conducting a TSCA section 6 risk evaluation for the ongoing uses of

asbestos. If a finding of unreasonable risk of injury to health or the environment is determined for any of those ongoing uses listed in Table 3, the Agency is required by statute to pursue risk management action options, including prohibitions on use. Risk management action by the Agency must be proposed within 1 year and finalized within 2 years of publication of the final asbestos risk evaluation document. For more information on the TSCA chemical risk evaluation process, read the *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* final rule (40 CFR 702, subpart B) (82 FR 33726, July 20, 2017) (FRL–9964–38).

In the absence of this rule, the manufacturing (including importing) or processing of asbestos (including as part of an article) for the significant new uses identified in this rule may begin at any time and without prior notice to EPA. EPA is committed to protecting the public from asbestos risks and is concerned that the commencement of the manufacturing (including importing) or processing for the significant new uses of asbestos identified in Table 1 could increase the volume of manufacturing (including importing) and processing of asbestos as well as the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA has concluded that action on this chemical substance is warranted and therefore determined that any manufacturing (including importing) or processing of asbestos (including as part of an article), using the definition under Title II of TSCA, for any use identified in Table 1 is a significant new use.

The Agency received several public comments on the proposed rule requesting that disposal and recycling of asbestos-containing products (EPA–HQ–OPPT–2018–0159–0437; EPA–HQ–OPPT–2018–0159–4066) as well as asbestos mining (EPA–HQ–OPPT–2018–0159–4023; EPA–HQ–OPPT–2018–0159–5886) be addressed. The Agency does not interpret the disposal of asbestos-containing materials to be processing for a significant new use; therefore, such activity does not require a significant new use notice under this final rule. Disposal is considered to be the end of life for a product. By contrast, however, the Agency does interpret recyling to be processing under TSCA, and recycling of any asbestos-containing material for a significant new use of asbestos subject to this rulemaking requires a SNUN. For example, recycling asbestos building material, such as roofing tiles, for reuse is prohibited without notification, review, and, as necessary, regulation by EPA.

The Agency interprets mining to be production under the TSCA definition of manufacture. Therefore, mining asbestos for a significant new use as identified in this rule would require a SNUN. Mining for the ongoing uses of asbestos, however, would not require a significant new use notice.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. If a person decides to begin manufacturing (including importing) or processing asbestos (including as part of an article) for a use identified in Table 1, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding the conditions of use.

B. Rationale for Making Inapplicable the Exemption at 40 CFR 721.45(f) for Persons Who Import or Process Asbestos

Chemical substances that are part of an article may still result in exposure if the chemical substance has certain physical-chemical properties—as in the case of asbestos, fibers can degrade with use and become friable over time where human exposures can occur leading to increased risks for disease (Ref. 6; Ref. 20; Ref. 21). During use and over time, non-friable asbestos has the potential to become friable (Ref. 6). For example, testing has shown that non-friable asbestos-containing material can become friable during use such as cutting, crumbling, and tearing, and as a result of such use, asbestos fibers can be released into the air (Ref. 20). Similarly, non-friable asbestos-containing building materials can release fibers if disturbed during building repair or demolition (Ref. 21). Therefore, EPA is making inapplicable the exemption at 40 CFR 721.45(f) for persons who import or process any asbestos as part of an article for the significant new uses of asbestos identified in Table 1. A person who imports or processes asbestos (including as part of an article) for a significant new use would be subject to the SNUN requirements in this rule. No person would be able to begin importing or processing asbestos (including as part of an article) for a significant new use without first submitting a SNUN to EPA and not before the Agency has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination, including a prohibition on use.

The Agency received several comments suggesting that exported asbestos-containing articles be subject to the notification requirement at TSCA section 12(b) (15 U.S.C. 2611(b)). Considering that this rulemaking addresses uses of asbestos (including as part of an article) that are no longer ongoing, the Agency sees no value in requiring export notification for the uses subject to this rule because such articles of asbestos are neither manufactured, imported, nor processed in the United States. Therefore, the Agency assumes that such articles are not exported. In the event EPA receives a notice for a significant new use of asbestos, the Agency will consider an export notification requirement for that significant new use at that time.

As for the ongoing uses of asbestos that are currently undergoing risk evaluation under TSCA section 6, the Agency feels it is appropriate to consider a TSCA section 12(b) export notification requirement as part of any risk management pursued after completion of the risk evaluation, if an unreasonable risk is determined.

C. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use of asbestos (including as part of an article) as designated in this rule:

1. EPA would receive notice of any person's intent to manufacture (including import) or process asbestos (including as part of an article) for the described significant new use before that activity begins.

2. EPA would have an opportunity to review and evaluate data submitted in a

SNUN before the notice submitter begins manufacturing (including importing) or processing asbestos (including as part of an article) for the described significant new use.

3. EPA would be able to either determine that the significant new use is not likely to present an unreasonable risk, or take necessary regulatory action associated with any other determination before the described significant new use of asbestos (including as part of an article) occurs.

IV. Significant New Use Determination

According to TSCA section 5(a)(2), EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.

2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

Both federal and state environmental protection agencies and occupational safety and health organizations provide existing regulation pertaining to certain aspects of the manufacturing (including importing), processing, use, and/or disposal of asbestos in order to protect consumers, workers, and the environment. EPA believes the significant new uses of asbestos identified in Table 1 could increase the volume of manufacturing (including importing) and processing of asbestos, as well as the duration and magnitude of human and environmental exposure to the substance and reintroduce exposure scenarios that have become obsolete over the past several decades. It is imperative that EPA be notified of any intended significant new use of asbestos identified in Table 1 and be provided the opportunity to evaluate such intended new use. Once a SNUR is finalized, failure to notify EPA and file a SNUN prior to manufacturing (including importing) or processing for a significant new use would constitute a violation of TSCA and would be subject to TSCA section 16 penalties, accordingly.

To determine what would constitute a significant new use of asbestos as discussed in this unit, EPA considered relevant information about the toxicity or expected toxicity of the substance, likely human exposures and environmental releases associated with possible uses, and the four factors listed in TSCA section 5(a)(2). In addition to the factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

The article exemption at 40 CFR 721.45(f) is based on an assumption that people and the environment will generally not be exposed to chemical substances in articles (Ref. 26). However, even when contained in an article, asbestos can become friable over time with use (Ref. 6; Ref. 20; Ref. 21). Based on this understanding, upon receipt of a SNUN, EPA intends to evaluate the potential risk of exposure to human health and the environment for any intended significant new use of asbestos (including as part of an article). This understanding warrants making the article exemption for submitting a SNUN at 40 CFR 721.45(f) inapplicable to importers or processors of articles containing asbestos. Considering the potential friability of asbestos, even when incorporated in articles, and the health risks associated with exposure to asbestos, EPA affirmatively finds under TSCA section 5(a)(5) that notification is justified by the reasonable potential for exposure to asbestos through the articles subject to this SNUR. EPA intends to evaluate such potential uses whether in the form of an article, or not, for any associated risks or hazards that might exist before those uses would begin. EPA has reason to anticipate that importing or processing asbestos as part of an article would create the potential for exposure to asbestos, and that EPA should have an opportunity to review the intended use before such use could occur.

V. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements. Provisions relating to user fees appear in 40 CFR part 700.

According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720.

Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacturing (including importing) or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's finding.

VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

EPA designates June 1, 2018 (the date of web posting of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule. In developing this rule, EPA has recognized that, given EPA's general practice of posting proposed and final SNURs on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before that publication.

Persons who began commercial manufacturing (including importing) or processing of the chemical substance (to include importing or processing articles and components thereof containing the chemical substance) for a significant new use as of June 1, 2018 would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until all TSCA prerequisites for the commencement of manufacturing (including importing) or processing have been satisfied (see 55 FR 17376, April 24, 1990 (FRL–3658–5) and 81 FR 85472, November 28, 2016 (FRL–9945–53) for additional information).

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not usually require developing new information (*e.g.,* generating test data) before submission of a SNUN; however, there is an exception: Development of information is required where the chemical substance subject to the SNUR is also subject to a rule, order, or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)). Also pursuant to TSCA section 4(h), which pertains to reduction of testing of vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies or NAMs), if available, to generate any recommended test data. EPA encourages dialogue with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required to submit only information in their

possession or control and to describe any other information known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include information that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacturing (including importing), processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific information it believes may be useful in evaluating a significant new use.

Submitting a SNUN that does not itself include information sufficient to permit a reasoned evaluation may increase the likelihood that EPA will either respond with a determination that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use or, alternatively, that in the absence of sufficient information, the manufacturing (including importing), processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on human exposure and environmental releases that may result from the significant new uses of the chemical substance.

VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what information may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems*.

The Agency received several public comments on the proposed asbestos SNUR requesting more explanation regarding the review process of a significant new use notice (EPA–HQ–OPPT–2018–0159–0437; EPA–HQ–OPPT–2018–0159–3224) and the opportunity for public comment on submitted SNUN applications, if any, as well as the Agency's significant new use determinations, if any, for asbestos (EPA–HQ–OPPT–2018–0159–4021; EPA–HQ–OPPT–2018–0159–1270; EPA–HQ–OPPT–2018–0159–5889). The SNUN submission and review process is explained in detail in the Response to Comments document (Ref. 3) and in this unit.

Anyone who plans to manufacture, import, or process asbestos (including as part of an article) for a significant new use identified in the rule is required by TSCA section 5 to provide EPA with notice at least 90 days before initiating the activity. A SNUN submission follows the same process as a PMN for new chemicals. Upon receipt of a significant new use notice, EPA is required by TSCA section 5(d)(2) to publish notification of the intended significant new use in the **Federal Register**. For transparency purposes, in addition, EPA intends to take public comment on any intended significant new use following that public notification.

In general, TSCA section 5 notices require that all reasonably ascertainable information on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure be included in the notice. In addition, EPA requires that the following information be submitted with the notice: Any health and environmental information in the possession or control of the submitter, parent company or affiliates, and a description of any other applicable information known to or reasonably ascertainable by the submitter (see 40 CFR 720.45 and 40 CFR 720.50 for specific requirements).

EPA risk assessors consider all of this information during the EPA significant new use review process and conduct a detailed analysis with the ultimate goal of identifying and controlling unreasonable risks. EPA uses an integrated approach that draws on knowledge and experience across disciplines to identify and evaluate concerns regarding human health and environmental effects, exposures and releases and impacts. EPA has developed assessment methods, databases, and predictive tools to evaluate what happens to chemicals when they are used and released to the environment and how workers, citizens, and the environment might be exposed to and affected by these chemicals. These tools are helpful when laboratory studies or monitoring data are not available or need to be supplemented. The Agency can take a range of actions, including prohibition, to ensure the use of the chemical does not present an unreasonable risk to human health or the environment.

SNUNs are reported using the standard electronic PMN form, which allows manufacturers of TSCA chemical substances to use the internet through EPA's Central Data Exchange (CDX), to submit TSCA section 5 notices to EPA (instructions available at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn*). SNUNs are subject to a 90-day review process similar to that for a PMN. When submitting a SNUN, the submitter should include a cover letter that provides the Code of Federal Regulations citation of the SNUR and identifies the specific significant new use(s) for which the SNUN is being submitted. The fee for each SNUN is $16,000, except for small businesses the fee is $2,800 (see 40 CFR 700.45).

IX. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substance included in this rule (Ref. 11). In the event that a SNUN is submitted, average costs are estimated at approximately $23,000 per SNUN submission for large business submitters and about $10,000 for small business submitters. These estimates include the cost to prepare and submit the SNUN (averaging about $7,300), and the payment of a user fee. Businesses that submit a SNUN would be subject to either a $16,000 user fee required by 40 CFR 700.45(c)(2)(ii), or, if they are a small business, a reduced user fee of $2,800 (40 CFR 700.45(c)(1)(ii)). Businesses that submit a SNUN are also estimated to incur average costs of $65 for rule familiarization. First time submitters will incur an average cost of $123 for CDX registration and associated activities. Companies manufacturing, importing, or processing asbestos or articles containing asbestos will incur an average cost of $79 for notifying their customers of SNUR regulatory activities. EPA's complete economic analysis is

available in the public docket for this rule (Ref. 11).

B. Export Notification

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. As explained in Unit I. and Unit III.B., export notifications are required for asbestos, but not for articles containing asbestos. Asbestos-containing articles are not subject to the export notification requirements; therefore, EPA assumes no additional costs under TSCA section 12(b) for this rule.

C. Import or Processing Chemical Substances as Part of an Article

In making inapplicable the exemption relating to persons that import or process certain chemical substances as part of an article, this action may affect firms that plan to import or process types of articles that may contain the asbestos. Some firms have an understanding of the contents of the articles they import or process. However, EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may need to become familiar with the requirements of the rule. And, while not required by the SNUR, these parties may take additional steps to determine whether the subject chemical substance is part of the articles they are considering for importing or processing. This determination may involve activities such as gathering information from suppliers along the supply chain and/or testing samples of the article itself. Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports or processes. Cost ranges are presented in the document entitled *Understanding the Costs Associated with Eliminating Exemptions for Articles in SNURs* (Ref. 27). Based on available information, EPA believes that article importers or processors that choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that importers or processors would take actions that are commensurate with the company's perceived likelihood that a chemical substance might be a part of an article for the significant new uses subject to this rulemaking (identified in Table 1) and the resources it has available. Example activities and their costs are provided in the accompanying Economic Analysis of this rule (Ref. 11).

X. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory action: Promulgate a TSCA section 8(a) Reporting Rule.

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they manufacture (including import) or process a chemical substance for a specific use or any use. However, for asbestos, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), that action would not ensure that EPA receives timely advance notice of future manufacturing (including importing) or processing of asbestos (including as part of an article and components thereof) for new uses that may produce changes in human and environmental exposures. Nor would action under 8(a) ensure that an appropriate determination (relevant to the risks of such manufacturing (including importing) or processing) has been issued prior to the commencement of such manufacturing (including importing) or processing. Furthermore, a TSCA section 8(a) rule would not ensure that manufacturing (including importing) or processing for the significant new use cannot proceed until EPA has responded to the circumstances by taking the required actions under TSCA sections 5(e) or 5(f) in the event that EPA determines any of the following: (1) That the significant new use presents an unreasonable risk under the conditions of use (without consideration of costs or other non-risk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); (2) that the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the significant new use; (3) that in the absence of sufficient information, the manufacture (including import), processing, distribution in commerce, use, or disposal of the substance, or any combination of such activities, may present an unreasonable risk (without consideration of costs or other non-risk factors, and including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA); or (4) that there is substantial production and sufficient potential for environmental release or human exposure (as defined in TSCA section 5(a)(3)(B)(ii)(II)).

In view of the level of health concerns about asbestos if used for a significant new use, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

XI. Scientific Standards, Evidence, and Available Information

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the science standards required under TSCA section 26(h), as applicable, to determine whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2). As noted in Unit III., EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use.

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this significant new use rule, in Unit II. and in the references cited throughout the preamble of this rule. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitively. The extent to which the various information, procedures, measures, methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

XII. Response to Public Comment

The Agency received a total of 17,912 comments in response to the proposed rule under docket ID number EPA–HQ–OPPT–2018–0159. The public comment period began on June 11, 2018 and ended August 10, 2018. Of the 17,912 public comments received, 11,732 are part of a mass mail campaign, 240 are from a second mass mail campaign, 67 are not posted in the public docket due to inappropriate language, and 5,873 individual comments are identified by

ID number, posted in the docket, and available to view on regulations.gov at *https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0159*.

Over 90% (5,386) of the individual comments received on the proposed Asbestos SNUR are anonymous. The majority of comments are generally considered not germane to the proposed rule considering the purpose and effect of the action, but, where appropriate, they are associated with one of the comment topics and addressed in EPA's Response to Comments document (Ref. 3). Upon careful review, EPA has identified the following seven general themes throughout the public comments:

1. The purpose of the proposed Asbestos SNUR.
2. Extend the comment period.
3. Ban asbestos.
4. Explain EPA's review process of Significant New Use Notices.
5. Provide clarification: Recycling and disposal.
6. Broaden the scope of the SNUR.
7. Economic Analysis.

EPA received thousands of comments pertaining to the purpose of the proposed Asbestos SNUR as well as the request that EPA ban the use of asbestos in the United States. Due to the overwhelming number of comments on these two topics, the Agency does not cite each relevant comment by ID number in the Response to Comments document. As for the other public comment topics of the proposed rule listed earlier in this unit, the Agency specifically cites in the Response to Comments document 17 substantive public comments, which may address multiple aspects of the proposed rule.

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket, EPA–HQ–OPPT–2018–0159, includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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XIV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011, and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be a regulatory action subject to Executive Order 13771 (82 FR 9339, February 3, 2017), because this action is not a significant regulatory action under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 *et seq.,* an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, as applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

This action does not impose any burden requiring additional OMB approval. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved under OMB control number 2070–0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved under OMB control number 2070–0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the burden is estimated to be approximately 100 hours per response (slightly less for submitters who have already registered to use the electronic submission system). This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required information.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not send any completed regulatory submissions to this address.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I certify that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a ''significant new use.'' By definition of the word ''new'' and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six-year period from 2005–2010, only three submitters self-identified as small in their SNUN submissions (Ref. 11). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL–5735–4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538, do not apply to this action.

F. Executive Order 13132: Federalism

This action will not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effect on 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have any effect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because EPA does not

believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This SNUR will prohibit the discontinued uses of asbestos from restarting without EPA having an opportunity to evaluate each intended use (*i.e.,* significant new use) for potential risks to health and the environment and take any necessary regulatory action, as appropriate.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have any effect on energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards and is therefore not subject to considerations under section 12(d) of NTTAA, 15 U.S.C. 272 note.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801–808, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Imports, Labeling, Occupational safety and health, Reporting and recordkeeping requirements.

Dated: April 17, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, add in numerical order under the undesignated center heading ''Significant New Uses of Chemical Substances'' and entry for ''721.11095'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Significant New Uses of Chemical Substances	
* * * * *	
721.11095	2070–0012
* * * * *	

* * * * *

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 4. Add § 721.11095 to read as follows:

§ 721.11095 Asbestos.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance identified as asbestos (as defined by 15 U.S.C. 2642(3) as the asbestiform varieties of chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section except as provided by paragraph (a)(3) of this section.

(2) Except as provided by paragraph (a)(3) of this section, the significant new use of the chemical substance identified in paragraph (a)(1) of this section is: Manufacturing (including importing) or processing for any of the following uses:

(i) Adhesives, sealants, roof and non-roof coatings;

(ii) Arc chutes;

(iii) Beater-add gaskets;

(iv) Cement products;

(v) Extruded sealant tape and other tape;

(vi) Filler for acetylene cylinders;

(vii) Friction materials;

(viii) High grade electrical paper;

(ix) Millboard;

(x) Missile liner;

(xi) Packings;

(xii) Pipeline wrap;

(xiii) Reinforced plastics;

(xiv) Roofing felt;

(xv) Separators in fuel cells and batteries;

(xvi) Vinyl-asbestos floor tile;

(xvii) Woven products;

(xviii) Other building products; or

(xix) Any other use of asbestos.

(3) *Exceptions.* (i) The significant new use identified in (a)(2) of this section does not include manufacturing (including importing) or processing for the following uses of the asbestiform variety of chrysotile (serpentine) asbestos:

(A) Diaphragms for use in chorine and sodium hydroxide production;

(B) Sheet gaskets for use in chemical manufacturing;

(C) Brake blocks in oil drilling equipment;

(D) Aftermarket automotive brakes/linings;

(E) Other vehicle friction products; or

(F) Other gaskets.

(ii) The significant new use does not include the manufacture (including importation) or processing of the asbestos-containing products identified in § 763.165, which continue to be prohibited pursuant to 40 CFR part 763, subpart I.

(b) *Specific requirements.* (1) 40 CFR 721.45(f) does not apply to this section. A person who intends to manufacture (including import) or process the substance identified in paragraph (a)(1) of this section for the significant new use identified in paragraph (a)(2) of this section as part of an article is subject to the notification provisions of § 721.25.

(2) Any person who submits a significant new use notice for the substance identified in paragraph (a)(1) of this section for the significant new

use identified in paragraph (a)(2) of this section must include with the notice adequate documentation or supporting information in the submitter's possession or control that the intended use is not subject to the prohibitions identified in 40 CFR part 763, subpart I.

[FR Doc. 2019–08154 Filed 4–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 25, and 30

[GN Docket No. 14–177; WT Docket No. 10–112; FCC 18–73]

Use of Spectrum Bands Above 24 GHz for Mobile Radio Services

Correction

In rule document 2018–14806 appearing on pages 34478–34492 in the issue of July 20, 2018, make the following correction:

§ 2.106 [Corrected]

■ On pages 34487–34488, the table is corrected to read as set forth below:

BILLING CODE 1301–00–D

24-24.05 AMATEUR AMATEUR-SATELLITE 5.150			24-24.05 5.150 US211	24-24.05 AMATEUR AMATEUR-SATELLITE 5.150 US211	ISM Equipment (18) Amateur Radio (97)
24.05-24.25 RADIOLOCATION Amateur Earth exploration-satellite (active) 5.150			24.05-24.25 RADIOLOCATION G59 Earth exploration-satellite (active) 5.150	24.05-24.25 Amateur Earth exploration-satellite (active) Radiolocation 5.150	RF Devices (15) ISM Equipment (18) Private Land Mobile (90) Amateur Radio (97)
24.25-24.45 FIXED	24.25-24.45 RADIONAVIGATION	24.25-24.45 FIXED MOBILE RADIONAVIGATION	24.25-24.45	24.25-24.45 FIXED MOBILE	RF Devices (15) Upper Microwave Flexible Use (30)
24.45-24.65 FIXED INTER-SATELLITE	24.45-24.65 INTER-SATELLITE RADIONAVIGATION 5.533	24.45-24.65 FIXED INTER-SATELLITE MOBILE RADIONAVIGATION 5.533	24.45-24.65 INTER-SATELLITE RADIONAVIGATION 5.533		RF Devices (15) Satellite Communications (25)
24.65-24.75 FIXED FIXED-SATELLITE (Earth-to-space) 5.532B INTER-SATELLITE	24.65-24.75 INTER-SATELLITE RADIOLOCATION-SATELLITE (Earth-to-space)	24.65-24.75 FIXED FIXED-SATELLITE (Earth-to-space) 5.532B INTER-SATELLITE MOBILE 5.533	24.65-24.75 INTER-SATELLITE RADIOLOCATION-SATELLITE (Earth-to-space)		
24.75-25.25 FIXED FIXED-SATELLITE (Earth-to-space) 5.532B	24.75-25.25 FIXED-SATELLITE (Earth-to-space) 5.535	24.75-25.25 FIXED FIXED-SATELLITE (Earth-to-space) 5.535 MOBILE	24.75-25.25	24.75-25.25 FIXED FIXED-SATELLITE (Earth-to-space) NG65 MOBILE	RF Devices (15) Satellite Communications (25) Upper Microwave Flexible Use (30)
25.25-25.5 FIXED INTER-SATELLITE 5.536 MOBILE Standard frequency and time signal-satellite (Earth-to-space)			25.25-25.5 FIXED INTER-SATELLITE 5.536 MOBILE Standard frequency and time signal-satellite (Earth-to-space)	25.25-25.5 Inter-satellite 5.536 Standard frequency and time signal-satellite (Earth-to-space)	RF Devices (15)
25.5-27 EARTH EXPLORATION-SATELLITE (space-to-Earth) 5.536B FIXED INTER-SATELLITE 5.536 MOBILE SPACE RESEARCH (space-to-Earth) 5.536C Standard frequency and time signal-satellite (Earth-to-space) 5.536A			25.5-27 EARTH EXPLORATION-SATELLITE (space-to-Earth) FIXED INTER-SATELLITE 5.536 MOBILE SPACE RESEARCH (space-to-Earth) Standard frequency and time signal-satellite (Earth-to-space) 5.536A US258	25.5-27 SPACE RESEARCH (space-to-Earth) Inter-satellite 5.536 Standard frequency and time signal-satellite (Earth-to-space) 5.536A US258	Page 54

[FR Doc. C1–2018–14806 Filed 4–24–19; 8:45 am]
BILLING CODE 1301–00–C

Proposed Rules

Federal Register
Vol. 84, No. 80
Thursday, April 25, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2011–BT–NOA–0013]

Energy Conservation Program: Data Collection and Comparison With Forecasted Unit Sales of Five Lamp Types

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

ACTION: Notification of data availability.

SUMMARY: The U.S. Department of Energy (DOE) is informing the public of its collection of shipment data and creation of spreadsheet models to provide comparisons between 2018 unit sales and benchmark estimate unit sales of five lamp types (*i.e.,* rough service lamps, vibration service lamps, 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps). For 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, the 2018 sales are not greater than 200 percent of the forecasted estimates. The 2018 unit sales for vibration service lamps are greater than 200 percent of the benchmark unit sales estimate. The 2018 unit sales for rough service lamps are below the benchmark unit sales estimate. DOE has prepared, and is making available on its website, a spreadsheet showing the comparisons of projected sales versus 2018 sales, as well as the model used to generate the original sales estimates.

DATES: April 25, 2019.

ADDRESSES: The spreadsheet is available online at: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=16*.

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: *five_lamp_types@ee.doe.gov*.

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background

The Energy Independence and Security Act of 2007 (EISA 2007; Pub. L. 110–140) was enacted on December 19, 2007. Among the requirements of subtitle B (Lighting Energy Efficiency) of title III of EISA 2007 were provisions directing DOE to collect, analyze, and monitor unit sales of five lamp types (*i.e.,* rough service lamps, vibration service lamps, 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps). In relevant part, section 321(a)(3)(B) of EISA 2007 amended section 325(l) of the Energy Policy and Conservation Act of 1975 (EPCA) by adding paragraph (4)(B), which generally directs DOE, in consultation with the National Electrical Manufacturers Association (NEMA), to: (1) Collect unit sales data for each of the five lamp types for calendar years 1990 through 2006 in order to determine the historical growth rate for each lamp type; and (2) construct a model for each of the five lamp types based on coincident economic indicators that closely match the historical annual growth rates of each lamp type to provide a neutral comparison benchmark estimate of future unit sales. (42 U.S.C. 6295(l)(4)(B)) Section 321(a)(3)(B) of EISA 2007 also amends section 325(l) of EPCA by adding paragraph (4)(C), which, in relevant part, directs DOE to collect unit sales data for calendar years 2010 through 2025, in consultation with NEMA, for each of the five lamp types. DOE must then compare the actual lamp sales in that year with the benchmark estimate. (42 U.S.C. 6295(l)(4)(C)) If DOE finds that the unit sales for a given lamp type in any year between 2010 and 2025 exceed the benchmark estimate of unit sales by at least 100 percent (*i.e.,* are greater than 200 percent of the anticipated sales), DOE must issue a finding within 90 days of the end of the analyzed calendar year that the estimate has been exceeded. (42 U.S.C. 6295(l)(4)(D)(i)(I), (E)(i)(I), (F)(i)(I), and (H)(i)(I)) [1]

On December 18, 2008, DOE issued a notification of data availability (NODA) for the *Report on Data Collection and Estimated Future Unit Sales of Five Lamp Types* (hereafter the ''2008 analysis''), which was published in the **Federal Register** on December 24, 2008. 73 FR 79072. The 2008 analysis presented the 1990 through 2006 shipment data collected in consultation with NEMA, the spreadsheet model DOE constructed for each lamp type, and the benchmark unit sales estimates for 2010 through 2025. On April 4, 2011, DOE published a NODA in the **Federal Register** announcing the availability of updated spreadsheet models presenting the benchmark estimates from the 2008 analysis and the collected sales data from 2010 for the first annual comparison. 76 FR 18425. Similarly, DOE published six NODAs in the **Federal Register** in the following seven years announcing the updated spreadsheet models and sales data for the annual comparisons. 77 FR 16183 (March 20, 2012); 78 FR 15891 (March 13, 2013); 79 FR 15058 (March 18, 2014); 80 FR 13791 (March 17, 2015); 81 FR 20261 (April 7, 2016); 83 FR 36479 (July 30, 2018; contained 2016 and 2017 data). This NODA presents the eighth comparison; specifically, section IV of this report compares the actual unit sales against benchmark unit sales estimates for 2018.[2]

[1] For 2,601–3,300 lumen general service incandescent lamps, EPCA does not specify a requirement to publish such findings, but as discussed further in this notification, EPCA does establish requirements upon the benchmark estimate being exceeded.

[2] The notifications and related documents for the 2008 analysis and successive annual comparisons,

EISA 2007 also amended section 325(l) of EPCA by adding paragraphs (4)(D) through (4)(H), which state that if DOE finds that the unit sales for a given lamp type in any year between 2010 and 2025 exceed the benchmark estimate of unit sales by at least 100 percent (*i.e.,* are greater than 200 percent of the anticipated sales), then DOE must take regulatory action for such lamps. (42 U.S.C. 6295(l)(4)(D) through (H)) For 2,601–3,300 lumen general service incandescent lamps, DOE must impose a statutorily prescribed maximum-wattage level and packaging requirement. (42 U.S.C. 6295(l)(4)(G)) For the other four types of lamps, the statute requires DOE to initiate an accelerated rulemaking to establish energy conservation standards. If the Secretary does not complete the accelerated rulemakings within one year from the end of the previous calendar year, EPCA specifies maximum wattage and related requirements (*i.e.,* a ''backstop requirement'') for each lamp type. (42 U.S.C. 6295(l)(4)(D)(ii), (E)(ii), (F)(ii), and (H)(ii))

As in the 2008 analysis and previous comparisons, DOE uses manufacturer shipments as a surrogate for unit sales in this NODA because manufacturer shipment data are tracked and aggregated by the trade organization, NEMA. DOE believes that annual shipments track closely with actual unit sales of these five lamp types, as DOE presumes that retailer inventories remain constant from year to year. DOE believes this is a reasonable assumption because the markets for these five lamp types have existed for many years, thereby enabling manufacturers and retailers to establish appropriate inventory levels that reflect market demand. In addition, increasing unit sales must eventually result in increasing manufacturer shipments. This is the same methodology presented in DOE's 2008 analysis and subsequent annual comparisons, and DOE did not receive any comments challenging this assumption or the general approach.

II. Definitions

A. Rough Service Lamps

Section 321(a)(1)(B) of EISA 2007 amended section 321(30) of EPCA by adding the definition of a ''rough service lamp.'' A ''rough service lamp'' means a lamp that—(i) has a minimum of 5 supports with filament configurations that are C–7A, C–11, C–17, and C–22 as listed in Figure 6–12 of the 9th edition of the IESNA [Illuminating Engineering Society of North America] Lighting handbook, or similar configurations where lead wires are not counted as supports; and (ii) is designated and marketed specifically for ''rough service'' applications, with—(I) the designation appearing on the lamp packaging; and (II) marketing materials that identify the lamp as being for rough service. (42 U.S.C. 6291(30)(X))

As noted above, rough service incandescent lamps must have a minimum of five filament support wires (not counting the two connecting leads at the beginning and end of the filament), and must be designated and marketed for ''rough service'' applications. This type of incandescent lamp can be used in applications where the lamp would be subject to mechanical shock or vibration while it is operating. Other incandescent lamps have only two support wires (which also serve as conductors), one at each end of the filament coil. When operating (*i.e.,* when the tungsten filament is glowing so hot that it emits light), rough service applications could cause an incandescent lamp's filament to break prematurely. To address this problem, lamp manufacturers developed lamp designs that incorporate additional support wires along the length of the filament to ensure that it has support not just at each end, but at several other points as well. The additional support protects the filament during operation and enables longer operating life for incandescent lamps in rough service applications.

B. Vibration Service Lamps

Section 321(a)(1)(B) of EISA 2007 amended section 321(30) of EPCA by adding the definition of a ''vibration service lamp.'' A ''vibration service lamp'' means a lamp that—(i) has filament configurations that are C–5, C–7A, or C–9, as listed in Figure 6–12 of the 9th Edition of the IESNA Lighting Handbook or similar configurations; (ii) has a maximum wattage of 60 watts; (iii) is sold at retail in packages of 2 lamps or less; and (iv) is designated and marketed specifically for vibration service or vibration-resistant applications, with—(I) the designation appearing on the lamp packaging; and (II) marketing materials that identify the lamp as being vibration service only. (42 U.S.C. 6291(30)(AA))

The statute mentions three examples of filament configurations for vibration service lamps in Figure 6–12 of the *IESNA Lighting Handbook,* one of which, C–7A, is also listed in the statutory definition of ''rough service lamp.'' The definition of ''vibration service lamp'' requires that such lamps have a maximum wattage of 60 watts and be sold at a retail level in packages of two lamps or fewer. Vibration service lamps must be designated and marketed for vibration service or vibration-resistant applications. As the name suggests, this type of incandescent lamp can be used in applications where the incandescent lamp would be subject to a continuous low level of vibration, such as in a ceiling fan light kit. In such applications, incandescent lamps without additional filament support wires may not achieve the full rated life, because the filament wire is brittle and would be subject to breakage at typical operating temperature. To address this problem, lamp manufacturers typically use a more malleable tungsten filament to avoid damage and short circuits between coils.

C. Three-Way Incandescent Lamps

Section 321(a)(1)(B) of EISA 2007 amended section 321(30) of EPCA by adding the definition of a ''3-way incandescent lamp.'' A ''3-way incandescent lamp'' includes an incandescent lamp that—(i) employs 2 filaments, operated separately and in combination, to provide 3 light levels; and (ii) is designated on the lamp packaging and marketing materials as being a 3-way incandescent lamp. (42 U.S.C. 6291(30)(Y))

Three-way lamps are commonly found in wattage combinations such as 50, 100, and 150 watts or 30, 70, and 100 watts. These lamps use two filaments (*e.g.,* a 30-watt and a 70-watt filament) and can be operated separately or together to produce three different lumen outputs (*e.g.,* 305 lumens with one filament, 995 lumens with the other, or 1,300 lumens using the filaments together). When used in three-way sockets, these lamps allow users to control the light level. Three-way incandescent lamps are typically used in residential multi-purpose areas, where consumers may adjust the light level to be appropriate for the task they are performing.

D. 2,601–3,300 Lumen General Service Incandescent Lamps

The statute does not provide a definition of ''2,601–3,300 Lumen General Service Incandescent Lamps;'' however, DOE is interpreting this term to be a general service incandescent lamp [3] that emits light between 2,601

including this NODA, are available through the DOE website at: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=16.*

[3] ''The term 'general service incandescent lamp' means a standard incandescent or halogen type lamp that—(I) is intended for general service applications; (II) has a medium screw base; (III) has a lumen range of not less than 310 lumens and not

Continued

and 3,300 lumens. These lamps are used in general service applications when high light output is needed.

E. Shatter-Resistant Lamps

Section 321(a)(1)(B) of EISA 2007 amended section 321(30) of EPCA by adding the definition of a ''shatter-resistant lamp, shatter-proof lamp, or shatter-protected lamp.'' ''Shatter-resistant lamp, shatter-proof lamp, and shatter-protected lamp'' mean a lamp that—(i) has a coating or equivalent technology that is compliant with NSF/ANSI 51 [National Sanitation Foundation/American National Standards Institute] and is designed to contain the glass if the glass envelope of the lamp is broken; and (ii) is designated and marketed for the intended application, with—(I) the designation on the lamp packaging; and (II) marketing materials that identify the lamp as being shatter-resistant, shatter-proof, or shatter-protected. (42 U.S.C. 6291(30)(Z)) Although the definition provides three names commonly used to refer to these lamps, DOE simply refers to them collectively as ''shatter-resistant lamps.''

Shatter-resistant lamps incorporate a special coating designed to prevent glass shards from being dispersed if a lamp's glass envelope breaks. Shatter-resistant lamps incorporate a coating compliant with industry standard NSF/ANSI 51,[4] ''Food Equipment Materials,'' and are labeled and marketed as shatter-resistant, shatter-proof, or shatter-protected. Some types of the coatings can also protect the lamp from breakage in applications subject to heat and thermal shock that may occur from water, sleet, snow, soldering, or welding.

III. Comparison Methodology

In the 2008 analysis, DOE reviewed each of the five sets of shipment data that was collected in consultation with NEMA and applied two curve fits to generate unit sales estimates for the five lamp types after calendar year 2006. One curve fit applied a linear regression to the historical data and extended that line into the future. The other curve fit applied an exponential growth function to the shipment data and projected unit sales into the future. For this calculation, linear regression treats the year as a dependent variable and shipments as the independent variable. The linear regression curve fit is modeled by minimizing the differences among the data points and the best curve-fit linear line using the least squares function.[5] The exponential curve fit is also a regression function and uses the same least squares function to find the best fit. For some data sets, an exponential curve provides a better characterization of the historical data, and, therefore, a better projection of the future data.

For 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, DOE found that the linear regression and exponential growth curve fits produced nearly the same estimates of unit sales (*i.e.,* the difference between the two forecasted values was less than 1 or 2 percent). However, for rough service and vibration service lamps, the linear regression curve fit projected lamp unit sales would decline to zero for both lamp types by 2018. In contrast, the exponential growth curve fit projected a more gradual decline in unit sales, such that lamps would still be sold beyond 2018, and it was, therefore, considered the more realistic forecast. While DOE was satisfied that either the linear regression or exponential growth spreadsheet model generated a reasonable benchmark unit sales estimate for 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, DOE selected the exponential growth curve fit for these lamp types for consistency with the selection made for rough service and vibration service lamps.[6] DOE examines the benchmark unit sales estimates and actual sales for each of the five lamp types in the following section and also makes the comparisons available in a spreadsheet online: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=16*.

IV. Comparison Results

A. Rough Service Lamps

On October 18, 2016, DOE published a notification announcing that the actual unit sales for rough service lamps were 219.7 percent of the benchmark estimate for the 2015 calendar year. 81 FR 71794, 71800.[7] Since unit sales for rough service lamps exceeded 200 percent of the benchmark estimate in 2015, and DOE did not complete an energy conservation standards rulemaking for these lamps by the end of calendar year 2016, the backstop requirement was triggered. DOE published a final rule on December 26, 2017 to adopt the statutory backstop requirements for rough service lamps which require that rough service lamps: (I) Have a shatter-proof coating or equivalent technology that is compliant with NSF/ANSI 51 and is designed to contain the glass if the glass envelope of the lamp is broken and to provide effective containment over the life of the lamp; (II) have a maximum 40-watt limitation; and (III) be sold at retail only in a package containing 1 lamp. 42 U.S.C. 6295(l)(4)(D)(ii)

DOE stated in the December 2017 final rule that it will continue to collect and model data for rough service lamps for two years after the effective date of January 25, 2018 (calendar years 2018 and 2019), in accordance with 42 U.S.C. 6295(l)(4)(I)(ii). 82 FR 60845, 60846 (December 26, 2017). For the 2018 calendar year, the exponential growth forecast projected the benchmark unit sales estimate for rough service lamps to be 4,268,000 units. The NEMA-provided shipment data reported shipments of 3,881,000 units in 2018, which is 90.9 percent of the benchmark estimate. DOE will complete its obligation to collect and model data for rough service lamps after the 2019 calendar year.

B. Vibration Service Lamps

On April 7, 2016, DOE published a notification announcing that the actual unit sales for vibration service lamps were 272.5 percent of the benchmark estimate for the 2015 calendar year. 81 FR 20261. Similar to rough service lamps, since unit sales for vibration service lamps exceeded 200 percent of the benchmark estimate in 2015, and DOE did not complete an energy conservation standards rulemaking for these lamps by the end of calendar year 2016, the backstop requirement was triggered. DOE published a final rule on December 26, 2017 to adopt the statutory backstop requirements for vibration service lamps which require that vibration service lamps: (I) Have a

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 (IV) 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)).

[4] NSF/ANSI 51 applies specifically to materials and coatings used in the manufacturing of equipment and objects destined for contact with foodstuffs.

[5] The least squares function is an analytical tool that DOE uses to minimize the sum of the squared residual differences between the actual historical data points and the modeled value (*i.e.,* the linear curve fit). In minimizing this value, the resulting curve fit will represent the best fit possible to the data provided.

[6] This selection is consistent with the previous annual comparisons. See DOE's 2008 forecast spreadsheet models of the lamp types for greater detail on the estimates.

[7] The October 2016 finding for rough service lamps was the result of a correction by NEMA to the data it initially submitted and relied upon by DOE for the April 7, 2016 notification. See, *https://www.regulations.gov/document?D=EERE-2013-BT-STD-0051-0075*.

maximum 40-watt limitation; and (II) be sold at retail only in a package containing 1 lamp. 42 U.S.C. 6295(l)(4)(E)(ii)

DOE stated in the December 2017 final rule that it will continue to collect and model data for vibration service lamps for two years after the effective date of January 25, 2018 (calendar years 2018 and 2019), in accordance with 42 U.S.C. 6295(l)(4)(I)(ii). 82 FR 60845, 60846 (December 26, 2017). For the 2018 calendar year, the exponential growth forecast projected the benchmark unit sales estimate for vibration service lamps to be 2,229,000 units. The NEMA-provided shipment data reported shipments of 4,723,000 units in 2018, which is 211.9 percent of the benchmark estimate. DOE will complete its obligation to collect and model data for vibration service lamps after the 2019 calendar year.

C. Three-Way Incandescent Lamps

For 3-way incandescent lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2018 to be 47,121,000 units. The NEMA-provided shipment data reported shipments of 22,098,000 units in 2018. As the NEMA-provided shipment data reported is only 46.9 percent the benchmark estimate, DOE will continue to track 3-way incandescent lamp sales data and will not initiate an accelerated standards rulemaking for this lamp type at this time.

D. 2,601–3,300 Lumen General Service Incandescent Lamps

For 2,601–3,300 lumen general service incandescent lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2018 to be 34,373,000 units. The NEMA-provided shipment data reported shipments of 2,465,000 units in 2018. As the NEMA-provided shipment data reported is only 7.2 percent of the benchmark estimate, DOE will continue to track 2,601–3,300 lumen general service incandescent lamp sales data and will not impose statutory requirements for this lamp type at this time.

E. Shatter-Resistant Lamps

For shatter-resistant lamps, the exponential growth forecast projected the benchmark unit sales estimate for 2018 to be 1,688,000 units. The NEMA-provided shipment data reported shipments of 400,000 units in 2018. As the NEMA-provided shipment data reported is only 23.7 percent of the benchmark estimate, DOE will continue to track shatter-resistant lamp sales data and will not initiate an accelerated standards rulemaking for this lamp type at this time.

V. Conclusion

This NODA compares the 2018 shipments against benchmark unit sales estimates for rough service lamps, vibration service lamps, 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps. For 3-way incandescent lamps, 2,601–3,300 lumen general service incandescent lamps, and shatter-resistant lamps, the 2018 sales are not greater than 200 percent of the forecasted estimates. The 2018 unit sales for vibration service lamps are greater than 200 percent of the benchmark unit sales estimate. The 2018 unit sales for rough service lamps are below the benchmark unit sales estimate. DOE will continue to monitor these lamp types and will assess 2019 unit sales next year.

Signed in Washington, DC, on April 18, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–08276 Filed 4–24–19; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0176; FRL–9992–65–Region 9]

Air Plan Approval; California; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of oxides of nitrogen (NO_X) from on-road heavy-duty vehicles. We are proposing to approve a local measure to reduce NO_X emissions from these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by May 28, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0176 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure 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. The 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For 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: Rynda Kay, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4118, *kay.rynda@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What measure did the State submit?

Table 1 lists the measure addressed by this proposal with the date that it was adopted by the California Air Resources Board (CARB). We refer to this measure as the ''South Coast Incentive Measure.''

TABLE 1—SUBMITTED MEASURE

Agency	Resolution No.	Measure title	Adopted	Submitted
CARB	18–3	South Coast On-Road Heavy-Duty Vehicle Incentive Measure	03/22/18	05/04/18

On November 4, 2018, the submittal for the South Coast Incentive Measure was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this measure?

There are no previous versions of the South Coast Incentive Measure in the SIP.

C. What is the purpose of the submitted measure?

Emissions of NO_X contribute to ground-level ozone, smog and particular matter, which harm human health and the environment. The CAA generally requires states to submit control measures to reduce NO_X emissions in ozone nonattainment areas.

On July 18, 1997, the EPA revised the national ambient air quality standard (NAAQS or ''standards'') for ozone to establish an 8-hour ozone standard of 0.08 parts per million (ppm).[1] Effective June 15, 2004, the EPA designated and classified the Los Angeles-South Coast Air Basin (''South Coast'') as a Severe nonattainment area for the 1997 ozone NAAQS.[2] On May 5, 2010, EPA reclassified the South Coast as an Extreme area for the 1997 ozone NAAQS with an attainment date of June 15, 2024.[3] The EPA has previously approved various SIP revisions submitted by California to provide for expeditious attainment of the 1997 ozone NAAQS in the South Coast and to meet other applicable planning requirements in the Clean Air Act.[4] The South Coast is also designated and classified as an Extreme nonattainment area for the 1-hour ozone NAAQS promulgated in 1979, the revised 8-hour ozone NAAQS promulgated in 2008, and the revised 8-hour ozone NAAQS promulgated in 2015.[5]

On April 27, 2017, CARB submitted the ''Final 2016 Air Quality Management Plan,'' March 2017 (''2016 AQMP'') and the ''Revised Proposed 2016 State Strategy for the State Implementation Plan,'' March 7, 2017 (''State SIP Strategy''), which contain, inter alia, a revised attainment demonstration and revised commitments to achieve specific amounts of emission reductions by 2023 for the 1997 ozone NAAQS. The 2016 AQMP also contains an attainment demonstration and commitments to achieve specific amounts of emission reductions by 2031 for the 2008 ozone NAAQS, in addition to revised attainment plan components for the 1979 1-hour ozone NAAQS. The purpose of the South Coast Incentive Measure is to satisfy a portion of the State's emission reduction commitments for the 1997 ozone NAAQS.

The South Coast Incentive Measure is a set of enforceable commitments by CARB to, among other things, monitor the SCAQMD's implementation of 1,300 on-road heavy-duty compression ignition truck repower and replacement projects during the 2019–2022 timeframe in the South Coast in accordance with specified portions of the Carl Moyer Program Guidelines, 2017 Revisions, approved April 27, 2017 (''2017 Carl Moyer Guidelines''). These program requirements ensure, among other things, that older, dirtier truck engines currently in operation in the South Coast will be replaced with less-polluting engines.

The South Coast Incentive Measure obligates CARB to achieve specific amounts of NO_X emission reductions through implementation of the program by a specific year, to submit annual reports to the EPA beginning on March 31, 2020, detailing its implementation of the program and the projected emission reductions, and to adopt and submit substitute measures by specific dates if the EPA determines that the program will not achieve the necessary emission reductions by the applicable implementation deadline.

We are proposing to approve the South Coast Incentive Measure into the California SIP and to make the obligations stated therein enforceable by the EPA and by citizens under the CAA. The State relies on the measure to achieve 1 ton per day of NO_X emission reductions in 2023 for purposes of meeting the requirements for attainment of the 1997 ozone NAAQS. We intend to evaluate California's submitted ozone attainment plans for South Coast through subsequent notice-and-comment rulemaking actions, as appropriate. The EPA's technical support document (TSD) has more information about this measure.

II. The EPA's Evaluation and Proposed Action

A. How is the EPA evaluating the measure?

Generally, SIP control measures must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

The CAA explicitly provides for the use of economic incentive programs (EIPs) as one tool for states to use to achieve attainment of the NAAQS.[6] EIPs use market-based strategies to encourage the reduction of emissions from stationary, area, and mobile sources in an efficient manner. EPA has promulgated regulations for statutory EIPs required under section 182(g) of the Act and has issued guidance for discretionary EIPs.[7]

The EPA's guidance documents addressing EIPs and other nontraditional programs provide for some flexibility in meeting established SIP requirements for enforceability and quantification of emission reductions, provided the State takes clear responsibility for ensuring that the emission reductions necessary to meet applicable CAA requirements are achieved. Accordingly, the EPA has consistently stated that nontraditional emission reduction measures submitted to satisfy SIP requirements under the Act must be accompanied by appropriate ''enforceable commitments'' from the State to monitor emission reductions achieved and to rectify

[1] 62 FR 38856 (July 18, 1997).

[2] 40 CFR 81.305, 69 FR 23858, 23888–89 (April 30, 2004).

[3] 75 FR 24409 (May 5, 2010).

[4] See, *e.g.,* 77 FR 12674 (March 1, 2012), 79 FR 52539 (September 3, 2014).

[5] 40 CFR 81.305, 77 FR 30088 (May 21, 2012), and 83 FR 25776 (June 4, 2018).

[6] See, *e.g.,* CAA sections 110(a)(2)(A), 172(c)(6), and 183(e)(4).

[7] 59 FR 16690 (April 7, 1994), codified at 40 CFR part 51, subpart U and EPA, ''Improving Air Quality with Economic Incentive Programs,'' January 2001 (''2001 EIP Guidance''). A ''discretionary economic incentive program'' is ''any EIP submitted to the EPA as an implementation plan revision for purposes other than to comply with the statutory requirements of sections 182(g)(3), 182(g)(5), 187(d)(3), or 187(g) of the Act.'' 40 CFR 51.491.

shortfalls in a timely manner.[8] The EPA has also consistently stated that, where a state intends to rely on a nontraditional program to satisfy CAA requirements, the state must demonstrate that the program achieves emission reductions that are quantifiable, surplus, enforceable, and permanent.[9]

Guidance documents that we use to evaluate discretionary EIPs and other nontraditional emission reduction programs include the following:

- ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs),'' Richard D. Wilson, Acting Assistant Administrator for Air and Radiation, October 24, 1997 (''1997 VMEP'').
- ''Improving Air Quality with Economic Incentive Programs'' January 2001 (EPA–452/R–01–001) (''2001 EIP Guidance'').
- ''Incorporating Emerging and Voluntary Measure in a State Implementation Plan (SIP),'' Stephen D. Page, OAQPS, October 4, 2004 (''2004 Emerging and Voluntary Measures Guidance'').
- ''Guidance on Incorporating Bundled Measures in a State Implementation Plan,'' Stephen D. Page, OAQPS, and Margo Oge, OTAQ, August 16, 2005 (''2005 Bundled Measures Guidance'').
- ''Diesel Retrofits: Quantifying and Using Their Emission Benefits in SIPs and Conformity: Guidance for State and Local Air and Transportation Agencies,'' February 2014 (EPA–420–B–14–007) (''2014 Diesel Retrofits Guidance'').

B. Does the measure meet the evaluation criteria?

The South Coast Incentive Measure contains clear, mandatory obligations that are enforceable against CARB and ensure that information about the emission reductions achieved through the program will be readily available to the public through CARB's submission of annual reports to the EPA. Our approval of the South Coast Incentive Measure would make these obligations enforceable by the EPA and by citizens under the CAA. The South Coast Incentive Measure obligates the State to implement a program that achieves quantifiable, surplus, permanent, and enforceable NO_X emission reductions and does not alter any existing SIP requirements. Our approval of this measure would strengthen the SIP and would not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements, consistent with the requirements of CAA section 110(l). Section 193 of the CAA does not apply to this action because this measure does not modify any SIP control requirement that was in effect before November 15, 1990.

We are proposing to find that the South Coast Incentive Measure satisfies CAA requirements for enforceability, SIP revisions, and nontraditional emission reduction programs as interpreted in EPA guidance documents. The TSD contains more information on our evaluation of this measure.

C. Proposed Action and Request for Public Comment

The EPA proposes to fully approve the submitted measure under CAA section 110(k)(3) based on a conclusion that the measure satisfies all applicable requirements. We will accept comments from the public on this proposal until May 28, 2019. If we take final action to approve the submitted measure, our final action will incorporate this measure into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the CARB measure described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials 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).

IV. 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 proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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 disproportionate human health or environmental effects with practical, appropriate, 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

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

[8] See, *e.g.,* EPA, ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs),'' Richard D. Wilson, Acting Assistant Administrator for Air and Radiation, October 24, 1997 (''1997 VMEP''), 4–5.

[9] See, *e.g.,* 2001 EIP Guidance, section 4.1.

Dated: April 4, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2019–08308 Filed 4–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0068; FRL–9992–70–Region 9]

Determination of Attainment by the Attainment Date; 2006 24-Hour Fine Particulate Matter National Ambient Air Quality Standard; Pinal County, Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the West Central Pinal County nonattainment area attained the 2006 24-hour national ambient air quality standard (NAAQS) for particulate matter with a diameter of 2.5 micrometers or smaller ($PM_{2.5}$ or ''fine particulate matter'') by December 31, 2017, the statutory attainment date for the area. The proposal is based on the three-year average of annual 98th percentile 24-hour concentrations for the 2015–2017 period, using complete, quality-assured, and certified $PM_{2.5}$ monitoring data.

DATES: Written comments must arrive on or before May 28, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0068 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure 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. The 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For 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: Jerry Wamsley, EPA Region IX, (415) 947–4111, *wamsley.jerry@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Background and Regulatory Context

This proposed action is related to the ongoing efforts of states and the EPA to implement the $PM_{2.5}$ NAAQS. Since the EPA's initial promulgation of the NAAQS to address fine particulate matter, there have been significant rulemaking and litigation developments that affect these ongoing efforts. To clarify the proper application of the statutory and regulatory requirements to this action, the EPA is providing a detailed explanation of $PM_{2.5}$ implementation efforts, nationally and in West Central Pinal County, Arizona.

On July 18, 1997, the EPA established the first NAAQS for $PM_{2.5}$ (''the 1997 $PM_{2.5}$ Standards''), including an annual standard of 15.0 micrograms per cubic meter (μg/m^3) based on a three-year average of annual mean $PM_{2.5}$ concentrations, and a 24-hour (or daily) standard of 65 μg/m^3 based on a three-year average of the 98th percentile of 24-hour concentrations.[1] The EPA established the 1997 $PM_{2.5}$ Standards based on significant evidence and numerous health studies demonstrating the serious health effects associated with exposures to $PM_{2.5}$. To provide guidance on the Clean Air Act (CAA) requirements for state and tribal implementation plans to implement the 1997 $PM_{2.5}$ Standards, the EPA promulgated the ''Final Clean Air Fine Particle Implementation Rule'' in October 2007 (hereinafter, the ''2007 $PM_{2.5}$ Implementation Rule'').[2] The Natural Resources Defense Council (NRDC) subsequently filed a petition for review challenging certain aspects of this rule.

On October 17, 2006, the EPA strengthened the 24-hour $PM_{2.5}$ NAAQS by revising it to 35 μg/m^3 and retained the level of the annual $PM_{2.5}$ standard at 15.0 μg/m^3.[3] Following promulgation of a new or revised NAAQS, the EPA is required by the CAA to promulgate designations for areas throughout the U.S. in accordance with section 107(d)(1) of the CAA. On November 13, 2009, the EPA designated 31 areas across the U.S. with respect to the revised 2006 24-hour $PM_{2.5}$ NAAQS, requiring states to prepare and submit attainment plans to meet those NAAQS.[4] At the time of the 2009 designations, the states and the EPA were operating under the interpretations of the CAA set forth in the 2007 $PM_{2.5}$ Implementation Rule, which covered issues such as the timing of attainment plan submissions, the content of attainment plan submissions, and the relevant attainment dates. The EPA deferred making a $PM_{2.5}$ designation for Pinal County, Arizona in its November 13, 2009 designations action.

On February 3, 2011, the EPA designated a portion of state lands in Pinal County, Arizona (''West Central Pinal County'') as nonattainment for the 2006 $PM_{2.5}$ NAAQS based on 2006–2008 data.[5] For more information on our designation of West Central Pinal County, see the February 3, 2011 final rule.[6] On October 26, 2012, the EPA designated nearby areas of Indian country of the Ak-Chin Indian Community and the Gila River Indian Community, which lie within the 2009 deferred area, as ''unclassifiable/attainment'' for the 2006 $PM_{2.5}$ NAAQS based on improved air quality.[7] These areas of Indian country are not addressed in this proposal.

On March 2, 2012, the EPA issued its ''Implementation Guidance for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards'' to provide guidance to states on the development of attainment plans to demonstrate attainment with the 2006 24-hour $PM_{2.5}$ NAAQS (''March 2012 Implementation Guidance'').[8] This

[1] 62 FR 38652 (July 18, 1997).

[2] 72 FR 20586 (April 25, 2007).

[3] 71 FR 61144 (October 17, 2006).

[4] 74 FR 58688 (November 13, 2009).

[5] 76 FR 6056 (February 3, 2011).

[6] The boundaries for the West Central Pinal County nonattainment area are described in 40 CFR 81.303.

[7] 77 FR 65310 (October 26, 2012).

[8] Memorandum dated March 2, 2012, from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to EPA Regional Air Directors, Regions I–X, ''Implementation Guidance for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National

guidance largely instructed states to rely on the 2007 $PM_{2.5}$ Implementation Rule in developing plans to demonstrate attainment of the 2006 24-hour $PM_{2.5}$ NAAQS. The EPA based the 2007 $PM_{2.5}$ Implementation Rule on the requirements of subpart 1, part D of title I of the CAA (''subpart 1'').

On January 4, 2013, the U.S. Court of Appeals for the D.C. Circuit issued its decision regarding the NRDC's legal challenge to the EPA's 2007 $PM_{2.5}$ Implementation Rule.[9] In *NRDC* v. *EPA,* the court held that the EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS pursuant only to the general implementation requirements of subpart 1, rather than also to the implementation requirements specific to coarse particulate matter (PM_{10}) in subpart 4, part D of title I of the CAA (''subpart 4''). The court reasoned that the plain meaning of the CAA requires implementation of the 1997 $PM_{2.5}$ NAAQS under subpart 4 because $PM_{2.5}$ falls within the statutory definition of PM_{10}; consequently, implementation of the $PM_{2.5}$ NAAQS is subject to the same statutory requirements as the PM_{10} NAAQS. The court remanded the rule and instructed the EPA ''to repromulgate these rules pursuant to Subpart 4 consistent with this opinion.'' [10]

Given the result of the *NRDC* v. *EPA* decision, the EPA withdrew its March 2012 Implementation Guidance for implementation of the 2006 24-hour $PM_{2.5}$ NAAQS. When withdrawing this guidance, the EPA advised states that the statutory requirements of subpart 4 apply to attainment plans for these NAAQS and reminded states about pre-existing EPA guidance regarding subpart 4 requirements. One practical consequence of the application of subpart 4 to states with areas designated nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS is that the applicable statutory attainment date is governed by CAA section 188(c), which states that for areas classified as Moderate, the statutory attainment date is ''as expeditiously as practicable, but no later than the end of the sixth calendar year after the area's designation as nonattainment.''

Consistent with the *NRDC* v. *EPA* decision, the EPA published a final rule on June 2, 2014, classifying all areas that were designated nonattainment for the 1997 and/or 2006 $PM_{2.5}$ standards at the time as Moderate under subpart 4.[11] The EPA also established a due date of December 31, 2014, for states to submit state implementation plan (SIP) revisions related to attainment and nonattainment new source review required for these areas pursuant to subpart 4. This rulemaking did not affect the statutory attainment dates imposed in subpart 4 and merely provided states with the opportunity to update or revise any prior attainment plan submissions, if necessary, to meet subpart 4 requirements considering the 2013 court decision. This rulemaking did not affect any action that the EPA had previously taken under CAA section 110(k) on a SIP for a $PM_{2.5}$ nonattainment area.

On September 4, 2013, EPA issued a clean data determination for the West Central Pinal County 2006 24-hour $PM_{2.5}$ nonattainment area based on three years of complete, quality-assured, and certified data for the 2010–2012 time frame.[12] The EPA's clean data determination suspended certain CAA requirements for the West Central Pinal County nonattainment area for so long as the area continues to attain the 2006 $PM_{2.5}$ NAAQS, including requirements to submit an attainment demonstration pursuant to section 189(a)(1)(B), the reasonably available control measure (RACM) provisions of section 189(a)(1)(C), the reasonable further progress (RFP) provisions of section 189(c), and related attainment demonstration, RACM, RFP and contingency measure provisions requirements of subpart 1, section 172.[13]

For an area classified as Moderate under the CAA, section 188(c) states that the statutory attainment date is ''as expeditiously as practicable, but no later than the end of the sixth calendar year after the area's designation as nonattainment.'' Therefore, the applicable attainment date for West Central Pinal County, designated nonattainment in 2011 and classified as Moderate in 2014, was December 31, 2017.[14] CAA section 188(b)(2) requires the EPA to determine whether any $PM_{2.5}$ nonattainment area classified as Moderate attained the relevant $PM_{2.5}$ NAAQS by the area's attainment date and requires the EPA to make such a determination within six months after that date. If that Moderate area has not attained the NAAQS by the relevant attainment date, then the CAA requires this area be reclassified to Serious. The 2006 24-hour $PM_{2.5}$ NAAQS is met when the 24-hour $PM_{2.5}$ design value at each eligible monitoring site is less than or equal to 35 $\mu g/m^3$, as explained further in Section II of this proposal.[15]

II. Criteria for Determining That an Area Has Attained the 2006 24-Hour $PM_{2.5}$ NAAQS

Under 40 CFR part 50, section 50.13 and in accordance with Appendix N, a nonattainment area meets the 2006 24-hour $PM_{2.5}$ NAAQS when the area's design value is less than or equal to 35 $\mu g/m^3$, based on the rounding convention in 40 CFR part 50, Appendix N, at each eligible monitoring site within the area. Our determination of whether an area's air quality meets the 2006 24-hour $PM_{2.5}$ NAAQS is generally based upon three years of complete, quality-assured data gathered at established state and local air monitoring stations (SLAMS) in a nonattainment area and entered into the EPA's Air Quality System (AQS) database.[16] Ambient air quality data must meet data completeness or substitution requirements for each year under consideration. The completeness requirements are met when at least 75 percent of the scheduled sampling days for each quarter have valid data.[17] Data from ambient air monitors operated by state or local agencies in compliance with the EPA monitoring requirements must be submitted to AQS. Monitoring agencies certify annually that these data are accurate to the best of their knowledge. Accordingly, the EPA relies primarily on data in AQS when determining the attainment status of areas.

III. The EPA's Proposed Action and Associated Rationale

The EPA's proposal is pursuant to the Agency's statutory obligation, under CAA section 188(b)(2), to determine whether the West Central Pinal County nonattainment area has attained the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2017. As discussed above in Section II, a nonattainment area must meet several criteria concerning its ambient data if the nonattainment area is to be determined as meeting the 2006

Ambient Air Quality Standards.'' This guidance was withdrawn June 6, 2013.

[9] *NRDC* v. *EPA,* 706 F. 3d 428 (D.C. Cir. 2013).

[10] Id. at 437.

[11] 79 FR 31566 (June 2, 2014).

[12] 78 FR 54394 (September 4, 2013).

[13] For a discussion of the Clean Data Determination for West Central Pinal County and our clean data policy as applied at that time, see our proposed rulemaking at 78 FR 41901 (July 12, 2013).

[14] 79 FR 31566, 31569, fn 5.

[15] An area's highest design value for the 24-hour $PM_{2.5}$ NAAQS is the highest of the three-year average of annual 98th percentile 24-hour average $PM_{2.5}$ mass concentration values recorded at each eligible monitoring site. See definition of ''Design values'' in 40 CFR part 50, Appendix N, 1.0(c).

[16] Because we are determining attainment of the $PM_{2.5}$ NAAQS as of December 31, 2017, in this proposal, the applicable 3-year data review period is 2015–2017. AQS is the EPA's national repository of ambient air quality data.

[17] 40 CFR part 50, Appendix N, section 4.2(b).

24-hour $PM_{2.5}$ NAAQS. These criteria include complete, quality-assured and certified data collected from a valid ambient air quality monitoring network and a design value calculated from the ambient data to be less than the applicable NAAQS. Our proposed action and rationale for our proposal are described below.

A. Data Completeness, Network Review, and Certification of Data

In accordance with 40 CFR part 50, Appendix N, a finding of attainment of the 2006 24-hour $PM_{2.5}$ NAAQS must generally be based upon complete, quality-assured data gathered at eligible monitoring sites in the nonattainment area and entered in the AQS. For the 24-hour $PM_{2.5}$ standards, Appendix N defines eligible monitoring sites as those that meet the technical requirements in 40 CFR 58.11 and 58.30. All data are reviewed to determine the area's air quality status in accordance with 40 CFR 50, Appendix N.[18]

The $PM_{2.5}$ ambient air quality monitoring data collected within the West Central Pinal County nonattainment area for the 2015–2017 three-year period must meet data completeness or substitution criteria according to 40 CFR part 50, Appendix N. The ambient air quality monitoring data completeness requirements are met when quarterly data capture rates for all four quarters in a calendar year are at least 75 percent. For the purposes of this proposal, we reviewed the data for the 2015–2017 period for completeness and determined that the $PM_{2.5}$ data collected by Pinal County met the completeness criterion for all 12 quarters at $PM_{2.5}$ monitoring sites in the West Central Pinal County nonattainment area.

The EPA's determination as to whether an area has attained the $PM_{2.5}$ NAAQS pursuant to CAA section 188(b)(2) is based on monitored ambient air quality data. The validity of this determination of attainment depends in part on whether the monitoring network adequately measures ambient $PM_{2.5}$ levels in the nonattainment area. Pinal County, Arizona, is the governmental agency with the authority and responsibilities under the State's laws for collecting ambient air quality data for the West Central Pinal County nonattainment area. Pinal County submits annual monitoring network plans to the EPA. These plans discuss the status of the air monitoring network, as required under 40 CFR part 58. The EPA reviews these annual network plans for compliance with the applicable reporting requirements in 40 CFR 58.10. With respect to $PM_{2.5}$, we have found that the annual network plans submitted by Pinal County meet the applicable requirements under 40 CFR part 58.[19] Furthermore, we concluded in our ''Technical Systems Audit Report'' of Pinal County's ambient air quality monitoring program that the ambient air monitoring network currently meets or exceeds the requirements for the minimum number of monitoring sites designated as SLAMS for $PM_{2.5}$ in the West Central Pinal County nonattainment area.[20] Pinal County certifies annually that the data it submits to AQS are quality-assured and has done so for each year relevant to our determination of attainment, 2015–2017.[21]

B. State and Local Air Monitoring Stations Site Replacement

In January 2016, Pinal County relocated the $PM_{2.5}$ SLAMS monitoring site operating at the Cowtown location and began operating a new $PM_{2.5}$ SLAMS monitoring site at the Hidden Valley location.[22] Beginning in late 2013, Pinal County and the EPA engaged in a cooperative multi-year process to review alternative locations and relocate the Cowtown $PM_{2.5}$ SLAMS monitoring site. Over the course of 2014 and 2015, Pinal County operated temporary monitors at two other potential monitoring site locations (*i.e.,* Hidden Valley; and White and Parker). This allowed Pinal County and the EPA to assess the data from each location and to determine if either of the proposed monitoring site locations met the applicable system modification requirements in 40 CFR part 58.14 for monitoring site relocation. Based on an assessment of $PM_{2.5}$ concentrations, land use, and nearby sources, the EPA approved the relocation of the Cowtown $PM_{2.5}$ SLAMS monitoring site to the new Hidden Valley location. Specifically, the EPA found that the Hidden Valley location provided the most similar concentrations from similar sources to the Cowtown monitoring site, thus meeting the requirement that a new location is, in fact, a nearby location with the same scale of representation. As noted in the EPA's approval, the data from the old and new monitoring site locations will be combined to form one continuous data record for design value calculations.[23] Consequently, the 2015–2017 design value is a composite data record consisting of 2015 data from the Cowtown monitoring site and 2016 and 2017 data from the Hidden Valley monitoring site.

C. Determination of Attainment

The EPA's evaluation of whether the West Central Pinal County nonattainment area has met the 2006 $PM_{2.5}$ 24-hour NAAQS is based on our review of the monitoring data, the adequacy of the $PM_{2.5}$ monitoring network in the nonattainment area, and the reliability of the data collected by the network, as discussed previously. Table 1 shows the annual 98th percentile concentrations for the years 2015–2017.[24] The design value for the 2015–2017 period is calculated as the average of the annual 98th percentiles for each of the three years according to 40 CFR 50, Appendix N, section 4.5. Table 1 shows the calculated 24-hour $PM_{2.5}$ design value for the Cowtown and Hidden Valley monitoring sites within the West Central Pinal County nonattainment area for the 2015–2017 period. The data show that the 24-hour design value for the 2015–2017 period, 32 $\mu g/m^3$, was equal to or less than 35 $\mu g/m^3$, the 2006 $PM_{2.5}$ 24-hour NAAQS. Thus, the EPA proposes to determine, based upon three years of complete, quality-assured and certified data from 2015–2017, that the West Central Pinal County nonattainment area has attained the 2006 24-hour $PM_{2.5}$ NAAQS by the applicable attainment date.

[18] For detailed descriptions of the EPA's data and monitoring requirements refer to 40 CFR 50.13; 40 CFR part 50, Appendix L; 40 CFR part 53; 40 CFR part 58, and 40 CFR part 58, appendices A, C, D, and E.

[19] We have included in our docket the correspondence transmitting our annual network reviews, *e.g.,* correspondence dated October 30, 2017, from Gwen Yoshimura, Manager, Air Quality Analysis Office, EPA Region IX, to Michael Sundblom, Director, Pinal County Air Quality Control District.

[20] We have included in our docket the correspondence concerning our audits, *e.g.,* correspondence dated September 28, 2016, from Elizabeth Adams, Division Director, Air Division, EPA Region IX, to Michael Sundblom, Director, Pinal County Air Quality Control District.

[21] We have included in our docket Pinal County's annual data certifications for 2015, 2016 and 2017, *e.g.,* correspondence dated April 30, 2018, from Josh DeZeeuw, Air Quality Manager, Pinal County Air Quality Control District, to Elizabeth Adams, Division Director, Air Division, EPA Region IX. Annual data certification requirements can be found at 40 CFR 58.15.

[22] The site identification numbers are as follows: Cowtown (AQS ID: 04–021–3013); and, Hidden Valley (AQS ID: 04–021–3015).

[23] For a complete discussion of the EPA's review and approval of the Cowtown monitoring site relocation, refer to correspondence dated October 22, 2015, from Meredith Kurpius, EPA Region IX, to Michael Sundblom, Pinal County Air Quality Control District, in the docket for this proposed rulemaking.

[24] AQS, Combined Site Sample Values Report, dated March 28, 2019, in the docket for this proposed rulemaking.

TABLE 1—WEST CENTRAL PINAL COUNTY NONATTAINMENT AREA DESIGN VALUE FOR THE 2006 $PM_{2.5}$ 24-HOUR NAAQS WITH ANNUAL 98TH PERCENTILE CONCENTRATIONS

[μg/m³]

Monitor	AQS Site ID No.	98th percentile			2015–2017 design value
		2015	2016	2017	
Cowtown	04–021–3013	22.6	.....	.....	32
Hidden Valley	04–021–3015	.....	34.0	38.2	.....

Source: AQS, Combined Site Sample Values Report, dated March 28, 2019.

IV. Summary of Our Proposed Action

Today, in accordance with section 188(b)(2) of the CAA, the EPA is proposing to determine that the West Central Pinal County Moderate nonattainment area attained the 2006 24-hour $PM_{2.5}$ NAAQS by its applicable attainment date, December 31, 2017. Our determination of attainment is based on complete, quality-assured and certified $PM_{2.5}$ monitoring data for the appropriate three-year period, 2015–2017. We are soliciting comments on this proposed determination of attainment by the attainment date.

If our proposal is finalized as proposed, West Central Pinal County will remain a Moderate nonattainment area and will not be reclassified to a Serious nonattainment area. A final rule determining that West Central Pinal County attained the 2006 24-hour $PM_{2.5}$ NAAQS by its applicable attainment date would not, however, constitute a redesignation of the area to attainment. States are required to meet several additional statutory requirements before the EPA can redesignate a nonattainment area to attainment of a NAAQS, including the EPA's approval of a state implementation plan demonstrating maintenance of the NAAQS for ten years after redesignation. The EPA is committed to working with states that submit redesignation requests for the 2006 24-hour $PM_{2.5}$ NAAQS. Our proposal today only addresses our statutory obligation to determine if the West Central Pinal County nonattainment area has attained the 2006 24-hour $PM_{2.5}$ NAAQS by its applicable attainment date, December 31, 2017.

V. Statutory and Executive Order Reviews

This action proposes to determine that the West Central Pinal County has met the 2006 24-hour $PM_{2.5}$ NAAQS as a statement of fact according to regulations and requirements discussed in the proposal. 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because this action is not significant under Executive Order 12866;
- 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 disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed determination 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 proposed determination 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxides, Fine particulate matter, Ammonia, Sulfur dioxides, Volatile organic compounds, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

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

Dated: April 15, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2019–08309 Filed 4–24–19; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0, 1, 51, 61, 63, and 69

[WC Docket Nos. 18–141, 17–144, 16–143, 05–25, and RM–10593; DA 19–281]

Wireline Competition Bureau Seeks Focused Additional Comment in Business Data Services and USTelecom Forbearance Petition Proceedings and Reopens Secure Data Enclave

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Wireline Competition Bureau reopens the secure data enclave, supplements the record in the business data services (BDS) and USTelecom proceedings with additional tables and information placed in the secure data enclave, and seeks focused comment on whether the additional data informs the extent of competition for transport.

DATES: Comments are due May 9, 2019 and reply comments are due May 16, 2019.

ADDRESSES: Participants in the price cap BDS proceedings previously authorized to access the secure data enclave

pursuant to the Protective Orders in the price cap BDS proceedings may request renewed access by emailing *SpecialAccess@fcc.gov*. Parties that were not previously authorized to access the secure data enclave must file an Acknowledgement of Confidentiality requesting access and send a copy to *SpecialAccess@fcc.gov*. For participants in the price cap BDS proceedings, instructions on requesting access to the secure data enclave are provided in a public notice released on November 5, 2018. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments and rely comments on or before the dates indicated on the first page of this document in dockets 17–144, 16–143, and 05–25. Procedures for using the Commission's Electronic Comment Filing System can be found in the *Second Further Notice*.

For participants in the USTelecom Forbearance Petition proceeding, the forthcoming protective order governing access to the secure data enclave for that proceeding will include instructions on requesting access to the secure data enclave and an Acknowledgement of Confidentiality that parties must execute and send to *SpecialAccess@fcc.gov*. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments and rely comments on or before the dates indicated on the first page of this document in docket 18–141. Procedures for using the Commission's Electronic Comment Filing System can be found in a public notice released on May 8, 2018.

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/*.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

People With Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: Christopher Koves, Pricing Policy Division, Wireline Competition Bureau at 202–418–8209 or by email at *Christopher.Koves@fcc.gov,* or Michele Levy Berlove, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1477 or via email at *Michele.Berlove@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of a document, WC Docket Nos. 18–141, 17–144, 16–143, 05–25; RM–10593, released on April 15, 2019. A full-text version of this document can be obtained at the following internet address: *https://www.fcc.gov/document/wcb-reopens-norc-and-seeks-comment-bds-and-ustelecom-proceedings*.

Synopsis

1. The Wireline Competition Bureau (Bureau) makes several announcements regarding the above-referenced dockets. First, the Bureau announces that it is supplementing the record in the price cap business data services (BDS) proceedings with tables and accompanying information prepared by the Office of Economics and Analytics, derived from highly confidential data from the *2015 Data Collection*. These tables and accompanying information show the distances from competitive provider fiber to incumbent local exchange carrier (LEC) wire centers and end user buildings with BDS demand in price cap areas (the *April Data Tables*). The Bureau seeks focused public comment on the extent to which the *April Data Tables* inform the extent of competition and competitive pressure in the market for lower speed (DS3 and below) time division multiplexing (TDM) transport services in price cap areas.

2. Second, to allow parties access to the *2015 Data Collection,* including the *April Data Tables,* and the opportunity to comment, the Bureau announces that it will (1) reopen the secure data enclave which will house these data upon publication of this document in the **Federal Register**; and (2) close it at the end of the comment and reply period established by this document, unless an interested party demonstrates a continuing need for access.

3. Third, pending the resolution of any objections to the Bureau incorporating the *2015 Data Collection* into the record of the USTelecom Forbearance Petition proceeding, the Bureau announces that it will also incorporate the *April Data Tables* into the record of that proceeding. The Bureau will allow access to the secure data enclave for parties in the USTelecom Forbearance Petition proceeding subject to a forthcoming protective order.

4. Fourth, the Bureau also seeks comment in the USTelecom Forbearance Petition proceeding on the extent to which the *2015 Data Collection,* including the *April Data Tables,* provide relevant information to evaluate USTelecom's request for forbearance from the requirements to provide transport as an unbundled network element (UNE) pursuant to section 251(c)(3) of the Act and section 51.319(d) of the Commission's rules. In addition, for the purposes of the USTelecom Forbearance Petition proceeding, the Bureau seeks comment on the public filings submitted in response to the *Second Further Notice and Further Notice* in the BDS proceedings, WC Docket Nos. 17–144, 16–143 and 05–25, since it was released on October 24, 2018.

5. The Bureau will place the *April Data Tables* in the secure data enclave which, pursuant to the protective orders in the price cap BDS proceedings, is the exclusive method for accessing highly confidential data submitted as part of the *2015 Data Collection*. Parties seeking to access the *April Data Tables* for purposes of participating in the price cap BDS proceedings must follow the procedures provided for in the Protective Orders in that proceeding for accessing highly confidential data. Those seeking access to the *April Data Tables* for purposes of participating in the USTelecom Forbearance Petition proceeding must follow the procedures set forth for accessing highly confidential data in the forthcoming protective order in that proceeding.

6. Participants in the price cap BDS proceedings previously authorized to access the secure data enclave pursuant to the Protective Orders in the price cap BDS proceedings may request renewed

access by emailing *SpecialAccess@fcc.gov*. Parties that were not previously authorized to access the secure data enclave must file an Acknowledgement of Confidentiality requesting access and send a copy to *SpecialAccess@fcc.gov*. For participants in the price cap BDS proceedings, instructions on requesting access to the secure data enclave are provided in a public notice released on November 5, 2018. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document in dockets 17–144, 16–143, and 05–25. Procedures for using the Commission's Electronic Comment Filing System can be found in the *Second Further Notice*.

7. For participants in the USTelecom Forbearance Petition proceeding, the forthcoming protective order governing access to the secure data enclave for that proceeding will include instructions on requesting access to the secure data enclave and an Acknowledgement of Confidentiality that parties must execute and send to *SpecialAccess@fcc.gov*. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document in docket 18–141. Procedures for using the Commission's Electronic Comment Filing System can be found in a public notice released on May 8, 2018.

8. *Paperwork Reduction Act.* This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

9. *Ex Parte Presentations.* This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by Rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

10. For further information, please contact Christopher Koves, Pricing Policy Division, Wireline Competition Bureau, at (202) 418–8209 or via email at *Christopher.Koves@fcc.gov,* or Michele Levy Berlove, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1477 or via email at *Michele.Berlove@fcc.gov*.

Federal Communications Commission.

Daniel Kahn,

Associate Bureau Chief, Wireline Competition Bureau.

[FR Doc. 2019–08139 Filed 4–24–19; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 84, No. 80
Thursday, April 25, 2019

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

Agricultural Marketing Service

[Document No. AMS–FTPP–19–0037]

Feasibility Study on Livestock Dealer Statutory Trust

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice: Request for information.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA), is soliciting comments on the feasibility of establishing a livestock dealer statutory trust.

DATES: Comments must be received by June 24, 2019.

ADDRESSES: Interested persons are invited to submit written comments via the internet at *http://www.regulations.gov* or to S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, Fair Trade Practices Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Room 2507, STOP 3601, Washington, DC 20250. Comments should make reference to the date and page number of this issue of the **Federal Register** and will be made available for public inspection at the above office during regular business hours.

Please be advised that all comments submitted in response to this notice will be included in the record and will be made available to the public on the internet via *http://www.regulations.gov*. Also, the identity of the individuals or entities submitting the comments will be made public.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, Fair Trade Practices Program, Agricultural Marketing Service, U.S. Department of Agriculture, telephone (202) 690–4355, email *s.brett.offutt@usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

Section 12103 of the Agriculture Improvement Act of 2018 (Pub. L. 115–334), the 2018 Farm Bill, charged the Secretary with conducting a study to determine the feasibility of establishing a livestock dealer statutory trust. Section 12103 requires that the study: (1) Analyze how the establishment of a livestock dealer statutory trust would affect buyer and seller behavior in markets for livestock (as defined in section 2(a) of the Packers and Stockyards Act, 1921 (7 U.S.C. 182)); (2) Examine how the establishment of a livestock dealer statutory trust would affect seller recovery in the event of a livestock dealer payment default; (3) Consider what potential effects a livestock dealer statutory trust would have on credit availability, including impacts on lenders and lending behavior and other industry participants; (4) Examine unique circumstances common to livestock dealers and how those circumstances could impact the functionality of a livestock dealer statutory trust; (5) Study the feasibility of the industry-wide adoption of electronic funds transfer or another expeditious method of payment to provide sellers of livestock protection from nonsufficient funds payments; (6) Assess the effectiveness of statutory trusts in other segments of agriculture, whether similar effects could be experienced under a livestock dealer statutory trust, and whether authorizing the Secretary to appoint an independent trustee under the livestock dealer statutory trust would improve seller recovery; (7) Consider the effects of exempting dealers with average annual purchases under a de minimis threshold from being subject to the livestock dealer statutory trust; and (8) Analyze how the establishment of a livestock dealer statutory trust would affect the treatment of sellers of livestock as it relates to preferential transfer in bankruptcy.

The study will be conducted by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS). AMS has regulatory authority over two statutes that contain statutory trusts: The Packers and Stockyards (P&S) Act and the Perishable Agricultural Commodities Act (PACA). The statutory PACA trust (7 U.S.C. 449e(c)) requires commission merchants, dealers, and brokers to hold perishable agricultural commodity inventory, products, receivables, and proceeds in trust for the benefit of unpaid produce sellers. The P&S Act currently includes two trusts: The packer trust (7 U.S.C. 196), which requires packers to hold livestock, inventory, receivables and proceeds in trust for unpaid cash sellers of livestock; and the poultry trust (7 U.S.C. 197), which requires live poultry dealers to hold poultry, inventories, receivables, and proceeds in trust for unpaid cash sellers or poultry growers.

The P&S Act also regulates the business practices of livestock dealers, but livestock dealers are not currently subject to a statutory trust provision. Section 301(d) of the P&S Act (7 U.S.C. 201), defines a ''dealer'' as ''any person, not a market agency, engaged in the business of buying or selling in commerce livestock, either on his own account or as the employee or agent of the vendor or purchaser.''

AMS is seeking comments to assist it in determining the feasibility of establishing a livestock dealer statutory trust. Commenters may address any or all of the eight (8) key components of the study by responding to the following questions:

(1) How would the establishment of a livestock dealer statutory trust affect buyer and seller behavior in markets for livestock?

(2) How would the establishment of a livestock dealer statutory trust affect seller recovery in the event of a livestock dealer payment default?

(3) What potential effects would a livestock dealer statutory trust have on credit availability, including impacts on lenders and lending behavior and other industry participants?

(4) How would the unique circumstances common to livestock dealers impact the functionality of a livestock dealer statutory trust?

(5) Is industry-wide adoption of electronic funds transfer or another expeditious method of payment feasible, and would such adoption provide sellers of livestock with protection from nonsufficient funds payments?

(6) How effective are statutory trusts in other segments of agriculture? Could similar effects be experienced under a

livestock dealer statutory trust? Would seller recovery improve if the Secretary was authorized to appoint an independent trustee under the livestock dealer statutory trust?

(7) Should dealers with average annual purchases under a de minimis threshold be exempt from being subject to the livestock dealer statutory trust? What purchase level should be considered for exemption? What effect would such an exemption have on the effectiveness of a livestock dealer statutory trust?

(8) How would the establishment of a livestock dealer statutory trust affect the treatment of sellers of livestock as related to preferential transfers in bankruptcy?

This notice provides for a 60-day period for interested parties to comment on the components of the study.

Authority: Sec. 12103, Pub. L. 115–334, 132 Stat. 4490.

Dated: April 22, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–08350 Filed 4–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

April 22, 2019.

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 (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden 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 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 May 28, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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: 7 CFR part 215—Special Milk Program for Children.

OMB Control Number: 0584–0005.

Summary of Collection: Section 3 of the Child Nutrition Act (CNA) of 1966 (Pub. L. 89–642, as amended; 42 U.S.C. 1772) authorizes the Special Milk Program (SMP) for Children. It provides for appropriation of such sums as may be necessary to enable the Secretary of Agriculture, under such rules and regulations as the Secretary may deem in the public interest, to encourage consumption of fluid milk by children in the United States in (1) nonprofit schools of high school grade and under, and (2) nonprofit nursery schools, child care centers, settlement houses, summer camps, and similar nonprofit institutions devoted to the care and training of children, which do not participate in a food service program authorized under the CNA or the National School Lunch Act.

Need and Use of the Information: The SMP is administered at the State, school food authority (SFA), and child care institution levels. The Food and Nutrition Service (FNS) collects information concerning the operation of the program including the submission of applications and agreements, submission and payment of claims, and the maintenance of records. Without this information FNS would not be able to reimburse schools and institutions in a timely manner to allow them to properly administer the program. In addition, data reporting would be delayed and the timely monitoring of program funding and program trends would be affected.

Description of Respondents: State, Local, and Tribal Government.

Number of Respondents: 3,499.

Frequency of Responses: Recordkeeping; Reporting: On Occasion, Monthly, and Annually.

Total Burden Hours: 13,325.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–08344 Filed 4–24–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0021]

Notice of Request for Reinstatement of an Information Collection; National Animal Health Monitoring System; Swine 2020 Study

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request the reinstatement of an information collection to conduct the National Animal Health Monitoring System's Swine 2020 Study.

DATES: We will consider all comments that we receive on or before June 24, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0021*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0021, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0021* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Swine 2020 Study, contact Mr. Bill Kelley, Program Analyst, Center for Epidemiology and Animal Health, VS, 2150 Centre Avenue, Building B, Fort Collins, CO 80524; (970) 494–7270. For more

detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: National Animal Health Monitoring System; Swine 2020 Study.

OMB Control Number: 0579–0315.

Type of Request: Reinstatement of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to protect the health of the livestock, poultry, and aquaculture populations in the United States by preventing the introduction and interstate spread of serious diseases and pests of livestock and for eradicating such diseases from the United States when feasible. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS).

In connection with this mission, APHIS operates the National Animal Health Monitoring System (NAHMS), which collects, on a national basis, statistically valid and scientifically sound data on the prevalence and economic importance of livestock, poultry, and aquaculture disease risk factors.

NAHMS' studies have evolved into a collaborative industry and government initiative to help determine the most effective means of preventing and controlling diseases of livestock. APHIS is the only agency responsible for collecting data on livestock health. Participation in any NAHMS study is voluntary, and all data are confidential.

APHIS plans to conduct the Swine 2020 Study as part of an ongoing series of NAHMS studies on the U.S. livestock population. This study will support the following objectives: (1) Describe current U.S. large-scale swine production practices for gestation, farrowing, nursery, grower/finisher, and wean-to-finish phases, specifically as they relate to housing, productivity, biosecurity, and morbidity and mortality prevention; (2) Describe current U.S. small-scale production practices including general management practices, housing practices, productivity, disease prevention, and mortality; (3) Determine the producer-reported prevalence of select respiratory, neurologic, gastrointestinal, systemic, and foodborne pathogens found in weaned market pigs; (4) Describe large-scale swine production antimicrobial-use patterns in pigs from post-weaning to market age; (5) Evaluate the presence of select pathogens and characterize isolated organisms from biological specimens (feces, oral fluids) in large-scale swine production; (6) Describe trends in small-scale swine health and disease management practices; (7) Describe trends in small-scale swine production system movements, marketing, and slaughter channels; and (8) Describe potential overlaps between small-scale swine production system movements with those of larger total confinement/commercial operations.

The two components of the study will be in-person questionnaire based surveys for large swine operations and computer-assisted telephone interviews for small swine operations. The large swine operation component will consist of two phases. In Phase I, the National Agricultural Statistics Service (NASS) will contact producers by telephone and personal interviews to collect operational level data and subordinate swine production site (locations where the animals are raised) contact information. NASS data collectors will follow up with producers at each swine production site by telephone and personal interviews to collect site level data and respondent consent to be contacted for Phase II of the study. In Phase II, APHIS data collectors will contact consenting respondents to administer questionnaires and perform biologic sampling. The small swine operation component of the study will consist of NASS sending producers questionnaires and following up via computer-assisted telephone interviews with those who do not respond.

The information collected through the Swine 2020 Study will be analyzed and used to predict or detect national and regional trends in disease emergence and movement such as the prevalence of clinical signs of coronavirus (*i.e.,* porcine epidemic diarrhea), Seneca Valley Virus, respiratory, and enteric disease in pigs; provide factual information on housing, marketing and movement for smaller swine operations; update national and regional production measures (such as average farrowing rate) for producer, veterinary, and industry reference; provide factual information on antimicrobial resistance among isolates obtained from feces; and provide assistance to researchers and the industry in evaluating the utility and accuracy of newer pathogen collection methods such as ropes to test saliva.

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

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

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.61 hours per response.

Respondents: Swine producers (large and small operations).

Estimated annual number of respondents: 10,205.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 18,407.

Estimated total annual burden on respondents: 11,168 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 22nd day of April 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–08351 Filed 4–24–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection: Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property

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 from all interested individuals and organizations on the new information

collection related to the Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property.

DATES: Comments must be received in writing on or before June 24, 2019 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Director, Lands and Realty Management, USDA Forest Service, 1400 Independence Ave. SW, Mailstop Code: 1124, Washington, DC 20250–1124. Comments also may be submitted via facsimile to 703–605–5117 or by email to: *reply_lands_staff@fs.fed.us*.

The public may inspect comments received at the Office of the Director, Lands, 1st Floor South East, Sidney R. Yates Federal Building, 201 14th Street SW, Washington, DC, during normal business hours. Visitors are encouraged to call ahead to 202–205–3563 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Mark Chandler, Realty Specialist, Lands and Realty Management, at 202–205–1117. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title: Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property.

OMB Number: 0596–NEW.

Expiration Date of Approval: N/A.

Type of Request: Revision of SF–299, *Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property,* into a common form.

Abstract: Section 6409 of the Middle Class Tax Relief and Job Creation Act of 2012 (Public Law 112–96) contains provisions directing the Administrator of the General Services Administration to develop a common form for applications for easements and rights-of-way for all executive agencies that shall be used by applicants with respect to the buildings or other property of each such agency. On June 14, 2012, the President signed Executive Order 13616, ''*Accelerating Broadband Infrastructure Deployment*''. Section 4 of Executive Order 13616 directed the General Services Administration (GSA) to develop and use one or more templates for uniform contract, application, and permit terms to facilitate nongovernment entities' use of Federal property for the deployment of broadband facilities. GSA created a Common Form Applications (GSA 3729). On January 8, 2018, the President signed Executive Order 13821, ''*Streamlining and Expediting Requests to Locate Broadband Facilities in Rural America,*'' which directed GSA to (1) evaluate the effectiveness of the GSA Common Form Application and (2) determine whether any revisions to the GSA Common Form Application were appropriate. GSA completed their evaluation of the use of the Common Form Application and determined that all other land management agencies were utilizing the SF–299 and not the Common Form Application. To ensure a coordinated and consistent approach across all agencies' GSA determined that with minor modifications, the SF–299 would serve as the standard application form for all agencies. The information collection requirements are necessary for the Forest Service to issue and administer special use authorizations that allow the public to use and occupy of National Forest System (NFS) lands under these authorities. The information collected is used by Forest Service officials (unless otherwise noted) to ensure that uses of NFS lands are authorized, in the public interest, and compatible with the Agency's mission; and/or record authorization of use granted by appropriate Forest Service officials.

In addition, the Department of the Interior (DOI) statutes for the Bureau of Land Management (BLM), Fish and Wildlife Service (FWS), National Park Service (NPS), and Bureau of Reclamation (BOR) along with the statutes for the U.S. Army Corp of Engineers (USACE), and the General Services Administration (GSA) authorize their collection of information who will utilize form SF–299 ''Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property.''

Several statutes authorize the Forest Service to issue and administer authorizations for use and occupancy of NFS lands and collect information from the public for those purposes. The laws authorizing the collection of this information include the Organic Administration Act of 1897 (16 U.S.C. 551); Title V of the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1761–1771); Act of March 4, 1915 (16 U.S.C. 497); Alaska Term Permit Act of March 30, 1948 (16 U.S.C. 497a); Act of September 3, 1954 (68 Stat. 1146; 43 U.S.C. 931c, 931d); National Forest Ski Area Permit Act (16 U.S.C. 497b); section 28 of the Mineral Leasing Act (30 U.S.C. 185); National Forest Roads and Trails Act (FRTA, 16 U.S.C. 532–538); section 7 of the Granger-Thye Act (16 U.S.C. 580d); Act of May 26, 2000 (16 U.S.C. 460l–6d); Federal Lands Recreation Enhancement Act (16 U.S.C. 6801–6814); Archeological Resource Protection Act of October 31, 1979 (16 U.S.C. 470aa–470mm); and the Rural Electrification Act of 1936, as amended.

Forest Service regulations implementing these authorities, found at 36 CFR part 251, subpart B, contain information collection requirements, including submission of applications, execution of forms, and imposition of terms and conditions that entail information collection requirements, such as the requirement to submit annual financial information, to prepare and update an operating plan; to prepare and update a maintenance plan, and to submit compliance reports and information updates.

The information helps the Forest Service identify the environmental and social impacts of special uses for purposes of compliance with the National Environmental Policy Act and program administration.

Information collection occurs via application forms, as well as terms and conditions in special use authorizations and operating plans. Information is required from proponents and applicants to evaluate proposals and applications to use or occupy NFS lands.

Special use authorizations encompass a variety of activities ranging from individual private uses to large-scale commercial facilities and public services. Examples of authorized special uses include public and private road rights-of-way, apiaries, domestic water supply conveyance systems, telephone and electric service rights-of-way, oil and gas pipeline rights-of-way, communications facilities, hydroelectric power-generating facilities, ski areas, resorts, marinas, municipal sewage treatment plants, and public parks and playgrounds.

SF–299, *Application for Transportation, Utility Systems, Telecommunications and Facilities on Federal Lands and Property,* is used to evaluate the applicant's technical and financial capability, nature of the proposed operations, and anticipated environmental impacts and proposed mitigation of those impacts. This form is used for most non-recreational NFS lands use requests. This form will also be used by the Department of the Interior's BLM, FWS, NPS, BOR, the USACE and GSA, to grant, issue, or renew rights-of-way (ROW) to use a specific piece of public land for a certain project.

Compliance Reports and Information Updates

Forest Service

Estimated Annual Burden: 8 burden hours per response.

Type of Respondents: Individuals, Businesses, Non-profit Organizations, and Non-Federal Governmental entities.

Estimated Annual Number of Respondents: 2,463 respondents.

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 submission request toward Office of Management and Budget approval.

Dated: April 11, 2019.

Allen Rowley,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–08320 Filed 4–24–19; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Minnesota Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Minnesota Advisory Committee (Committee) to the Commission will meet via conference call to discuss civil rights concerns in the State.

DATES: The meetings will be held on

- Wednesday May 15, 2019, at 2:30 p.m. CDT.
- Wednesday June 26, 2019, at 12 p.m. CDT.

Public Call Information: Dial: 1–877–260–1479; Conference ID: 5706237.

FOR FURTHER INFORMATION CONTACT: Carolyn Allen at *callen@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: This meetings are available to the public through the above toll-free call-in number. Any interested member of the public may call this number and listen to the meetings. Callers can expect to incur charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the U.S. Commission on Civil Rights, Regional Programs Unit, 230 S. Dearborn, Suite 2120, Chicago, IL 60604. They may be faxed to the Commission at (312) 353–8324, or emailed Carolyn Allen at *callen@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting on the Federal Advisory Committee database (facadatabase.gov), under the Minnesota Advisory Committee link. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of Minutes
III. Discussion: Racial Trauma and Civil Rights in Minnesota
IV. Public Comment
V. Next Steps
VI. Adjournment

Dated: April 22, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–08362 Filed 4–24–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Office of the Secretary, Office of Security; Submission for OMB Review; Comment Request; Foreign National Request Form

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Office of the Secretary, Office of Security (OSY), Commerce.

Title: Foreign National Request Form.

OMB Control Number: 0690–0033.

Form Number(s): 207–12–1.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 12,000.

Average Hours per Response: 15 minutes.

Burden Hours: 3,000.

Estimated Total Annual Cost to Public: $0.

Needs and Uses: The Office of Security is requesting clearance of this collection to gather information to mitigate variances in foreign access management program implementation and registration information requirements needed to reach risk-based determinations of physical and logical access by foreign national visitors and guests to Commerce facilities and resources. The information collected will be used for risk-based assessments of short-term access or as partial completion towards long term guest research agreements and supporting security and background investigations for potential personal identity credential issuance in compliance with U.S. laws and regulations governing physical and logical access to federal facilities and information resources. Due to the increasing diversity of foreign national participation in departmental programs, considerable efforts have been made to baseline requirements as a means to define uniform program standards as well as to expand current guidance beyond foreign visitor control to manage emerging risks associated with physical and logical access to the Department' s facilities and resources.

Affected Public: Individuals and households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

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

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–08324 Filed 4–24–19; 8:45 am]

BILLING CODE 3510–17–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Open Meeting

The Materials Technical Advisory Committee will meet on May 9, 2019, 10:00 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW, Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction.
2. Remarks from BIS senior management.
3. Presentation on 'HIS 101 and CPI 101'
4. Presentation on 'Toray Next Generation Prepreg Systems'
5. Report on regime-based activities.
6. Public Comments and New Business.

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than May 2, 2019.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

For more information, call Yvette Springer at (202) 482–2813.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2019–08334 Filed 4–24–19; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Technical Advisory Committee will meet on May 9, 2019, 10:00 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW, Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction.
2. Remarks from BIS senior management.
3. Presentation on 'HIS 101 and CPI 101'
4. Presentation on 'Toray Next Generation Prepreg Systems'
5. Report on regime-based activities.
6. Public Comments and New Business.

Closed Session

7. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ l0(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than May 2, 2019.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on April 19, 2019, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 § § 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2019–08335 Filed 4–24–19; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–888, C–570–105]

Carbon and Alloy Steel Threaded Rod From India and the People's Republic of China: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

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

DATES: Applicable April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Carrie Bethea at (202) 482–1491 (India), and Thomas Schauer at (202) 482–0410 (the People's Republic of China (China)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On March 13, 2019, the Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of carbon and alloy steel threaded rod from China and India.[1] Currently, the preliminary determinations are due no later than May 17, 2019.

[1] *See Carbon and Alloy Steel Threaded Rod from India and the People's Republic of China: Initiation of Countervailing Duty Investigations,* 84 FR 10040 (March 19, 2019) (*Initiation Notice*).

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) The petitioner [2] makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On March 29, 2019, the petitioner submitted timely requests that Commerce postpone the preliminary CVD determinations.[3] The petitioner stated that additional time is necessary to allow Commerce to select mandatory respondents and issue questionnaires, as well as to allow Commerce and the petitioner to review questionnaire responses and identify deficiencies; additional time will also permit Commerce to issue and receive supplemental questionnaires prior to the preliminary determinations.[4] In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the requests. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which these investigations were initiated, *i.e.,* July 22, 2019.[5] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: April 19, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–08345 Filed 4–24–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017

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

SUMMARY: The Department of Commerce (Commerce) determines that T.T. International Co., Ltd. (TTI) sold hydrofluorocarbon blends (HFCs) from the People's Republic of China (China) at less than normal value (NV) during the period of review (POR), February 1, 2016, through July 31, 2017.

DATES: Applicable April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Manuel Rey, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4987 or (202) 482–5518, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on September 11, 2018.[1] For events subsequent to the *Preliminary Results, see* Commerce's Issues and Decision Memorandum.[2] On December 17, 2018, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline for issuing the final results until March 11, 2019.[3] Further, Commerce exercised its discretion to toll all deadlines affected by the partial Federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[4] Therefore, the revised deadline for the final results is now April 19, 2019.

Scope of the Order

The products subject to this order are HFC blends. HFC blends covered by the scope are R–404A, a zeotropic mixture consisting of 52 percent 1,1,1 Trifluoroethane, 44 percent Pentafluoroethane, and 4 percent 1,1,1,2-Tetrafluoroethane; R–407A, a zeotropic mixture of 20 percent Difluoromethane, 40 percent Pentafluoroethane, and 40 percent 1,1,1,2-Tetrafluoroethane; R–407C, a zeotropic mixture of 23 percent Difluoromethane, 25 percent Pentafluoroethane, and 52 percent 1,1,1,2-Tetrafluoroethane; R–410A, a zeotropic mixture of 50 percent Difluoromethane and 50 percent Pentafluoroethane; and R–507A, an azeotropic mixture of 50 percent Pentafluoroethane and 50 percent 1,1,1-Trifluoroethane also known as R–507. The foregoing percentages are nominal percentages by weight. Actual percentages of single component refrigerants by weight may vary by plus or minus two percent points from the nominal percentage identified above.[5]

Analysis of Comments Received

In the Issues and Decision Memorandum, we addressed all issues raised in parties' case and rebuttal briefs. Appendix I to this notice provides a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and

[2] The petitioner is Vulcan Threaded Products Inc.

[3] *See* Letters from the petitioner, ''Carbon and Alloy Steel Threaded Rod from India: Request to Extend Preliminary Determination Deadline,'' dated March 29, 2019, and ''Carbon and Alloy Steel Threaded Rod from China: Request to Extend Preliminary Determination Deadline,'' dated March 29, 2019.

[4] *Id.*

[5] The actual deadline is July 21, 2019, which is a Sunday. In accordance with Commerce's practice, where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of* ''*Next Business Day*'' *Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[1] *See Hydrofluorocarbon Blends from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 83 FR 45890 (September 11, 2018) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Antidumping Duty Administrative Review: Hydrofluorocarbon Blends from the People's Republic of China; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Hydrofluorocarbon Blends from the People's Republic of China: Extension of Deadline for the Final Results of Antidumping Duty Administrative Review,'' dated December 17, 2018.

[4] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] For a complete description of the scope of the order, *see* Issues and Decision Memorandum issued concurrently with, and hereby adopted by, this notice.

is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html*. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the *Preliminary Results*

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain revisions to the margin calculations for TTI,[6] and to the rate assigned to the non-examined respondents receiving a separate rate.[7]

Separate Rates Respondents

In the *Preliminary Results,* we determined that TTI and three other companies demonstrated their eligibility for separate rates. We received no comments since the issuance of the *Preliminary Results* that provide a basis for reconsideration of these determinations.[8] Therefore, for these final results, we continue to find that the companies listed in the table in the ''Final Results'' section of this notice are eligible for separate rates.

Further, we determined in the *Preliminary Results* that six companies failed to demonstrate an absence of *de facto* government control; and, thus, Commerce did not grant them separate rates.[9] No party provided comments with respect to any of these six companies, and, thus, we continue to find that these six companies are not eligible for separate rates.

Rate for Non-Examined Separate-Rate Respondents

The statute and our regulations do not address the rate to be assigned to respondents not selected for individual examination when we limit our examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, we look to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents not individually examined in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference for not calculating an all-others rate using rates which are zero, *de minimis,* or based entirely on facts available.[10] Accordingly, we generally will determine the dumping margin for companies not individually examined by averaging the weighted-average dumping margins for the individually examined respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[11]

For the final results, we calculated a rate only for TTI. Therefore, for these final results, following the practice described above, we have assigned the rate calculated for TTI to the companies that have not been individually examined but have demonstrated their eligibility for a separate rate.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Daikin Fluorochemicals (China) Co., Ltd. (Daikin) and Zhejiang Yonghe Refrigerant Co., Ltd. (Zhejiang Yonghe) [12] had no shipments of subject merchandise during the POR. As we have not received any information to contradict our preliminary findings, we determine that Daikin and Zhejiang Yonghe had no shipments of subject merchandise during the POR, and we intend to issue appropriate instructions to U.S. Customs and Border Protection (CBP) that are consistent with our ''automatic assessment'' clarification for these final results of review.

Final Results of the Administrative Review

Because Arkema, Dongyang Weihua, Sinochem Taicang, Weitron, Zhejiang Lantian, and Zhejiang Quzhou did not demonstrate that they are entitled to a separate rate, Commerce finds these six companies to be part of the China-wide entity. Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[13] we did not conduct a review of the China-wide entity. The rate previously established for the China-wide entity is 216.37 percent [14] and is not subject to change as a result of this review.

For companies subject to this review and established their eligibility for a separate rate, Commerce determines that the following weighted-average dumping margins exist for the period February 1, 2016, through July 31, 2017:

Exporter	Weighted-average dumping margin (percent)
T.T. International Co., Ltd	285.73
Shandong Huaan New Material Co., Ltd*	285.73
Zhejiang Sanmei Chemical Industry Co. Ltd*	285.73
Jinhua Yonghe Fluorochemical Co., Ltd*	285.73

*This company was not selected as a mandatory respondent but is subject to this administrative review and demonstrated that it qualified for a separate rate during the POR.

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 covered by this review. Commerce intends to issue assessment instructions to CBP 15 days

[6] *See* Memorandum ''Calculation Memorandum for the Final Results of the Administrative Review of Hydrofluorocarbon Blends from the People's Republic of China Memo for TTI International Co., Ltd.,'' dated concurrently with this notice.

[7] *See* Issues and Decision Memorandum for a summary of these revisions.

[8] We note, however, that we made a ministerial error when identifying the name of one of these companies in the *Preliminary Results.* For further discussion, *see* the Issues and Decision Memorandum at Comment 1.

[9] These companies are: (1) Arkema Daikin Advanced Fluorochemicals (Changsu) Co., Ltd. (Arkema); (2) Dongyang Weihua Refrigerants Co., Ltd. (Dongyang Weihua); (3) Sinochem Environmental Protection Chemicals (Taicang) Co., Ltd. (Sinochem Taicang); (4) Weitron International Refrigeration Equipment (Kunshan) Co., Ltd. (Weitron); (5) Zhejiang Lantian Environmental Protection Fluoro Material Co. Ltd. (Zhejiang Lantian); and (6) Zhejiang Quzhou Lianzhou Refrigerants Co., Ltd. (Zhejiang Quzhou).

[10] *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[11] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[12] In the *Preliminary Results,* Commerce inadvertently identified this company as Jinhua Yonghe Fluorochemical Co., Ltd. For further discussion, *see* the Issues and Decision Memorandum at Comment 1.

[13] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity (NME) in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

[14] *See Hydrofluorocarbon Blends and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436, 55438 (August 19, 2016).

after the date of publication of these final results of review.

For TTI, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1). Where an importer- (or customer-) specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[15]

Pursuant to Commerce's assessment practice, for entries that were not reported in the U.S. sales data submitted by TTI, we will instruct CBP to liquidate such entries at the China-wide rate.[16] Similarly, because Commerce determined that Daikin and Zhejiang Yonghe had no shipments of the subject merchandise, any suspended entries of subject merchandise from Daikin and Zhejiang Yonghe will also be liquidated at the China-wide rate.[17]

For the respondents which were not selected for individual examination in this administrative review and which qualified for a separate rate, the assessment rate will be equal to the weighted-average dumping margin determined for TTI in the final results of this administrative review.

For the companies found to be part of the China-wide entity, because Commerce determined that these companies did not qualify for a separate rate, we will instruct CBP to assess dumping duties on the companies' entries of subject merchandise at the rate of 216.37 percent.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review; (2) for previously investigated or reviewed China and non-China exporters not listed above that currently have a separate rate, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding where the exporter received that separate rate; (3) for all China exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity, 216.37 percent; and (4) for all non-China exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Notifications to Importers

This notice also serves as a final 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 the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notifications to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 19, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

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Comment 4: Adjusting Global Trade Atlas Import Data for Movement Expenses
Comment 5: Surrogate Values (SVs) for R–32 and R–143a
Comment 6: SV for Anhydrous Hydrogen Fluoride
Comment 7: Surrogate Financial Statements
Recommendation

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[15] *See* 19 CFR 351.106(c)(2).

[16] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[17] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–017]

Countervailing Duty Order on Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2016

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

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers/exporters of passenger vehicle and light truck tires from the People's Republic of China (China) during the period of review (POR) January 1, 2016, through December 31, 2016.

DATES: Applicable April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** on September 10, 2018.[1] We invited interested parties to comment on the *Preliminary Results*. On October 31, 2018, we received case briefs from the following interested parties: Cooper (Kunshan) Tire Co., Ltd. (Cooper); Qingdao Sentury Tire Co. Ltd. (Sentury); and the Government of China (GOC). No party submitted rebuttal

[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission, in Part; 2016,* 83 FR 45611 (September 10, 2018) (*Preliminary Results*).

briefs. On December 17, 2018, Commerce extended the period for issuing the final results of this review until February 7, 2019. Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[2] This extended the deadline for the final results to March 19, 2019. On March 13, 2019, Commerce extended the period for issuing the final results an additional 30 days. The revised deadline for the final results is now April 18, 2019.

Scope of the Order

The products covered by the order are certain passenger vehicle and light truck tires from the China. A full description of the scope of the order is contained in the Issues and Decision Memorandum.[3]

Analysis of Comments Received

All issues raised in interested parties' briefs are addressed in the Issues and Decision Memorandum accompanying this notice. 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 *https://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be access directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on case briefs, and all supporting documentation, we made certain changes from the *Preliminary Results*. Commerce has adjusted the synthetic rubber and butadiene benchmarks for Cooper, adjusted the ocean freight rates used to construct the benchmark for carbon black and nylon cord for Cooper, and corrected various ministerial errors for both respondents. These changes are explained in 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 to be 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 that the subsidy is specific.[4] For a full description of the methodology underlying all of Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), we calculated a countervailable subsidy rate for the mandatory respondents, Cooper and Sentury. For the non-selected companies subject to this review,[5] we followed Commerce's practice, which is to base the subsidy rates on an average of the subsidy rates calculated for those companies selected for individual review, excluding *de minimis* rates or rates based entirely on adverse facts available.[6] In this case, for the non-selected companies, we have calculated a rate by weight-averaging the calculated subsidy rates of Cooper and Sentury using their publicly-ranged sales data for exports of subject merchandise to the United States during the POR. We find the countervailable subsidy rates for the producers/exporters under review to be as follows:

Company	Subsidy rate (%)
Cooper (Kunshan) Tire Co., Ltd. (Cooper)	16.37
Qingdao Sentury Tire Co. Ltd. (Sentury)	15.75
Non-Selected Companies Under Review	16.17

Disclosure

We will disclose to the parties in this proceeding the calculations performed for these final results within five days of the date of publication of this notice in the **Federal Register**.[7]

Assessment Rates

Consistent with 19 CFR 351.212(b)(2), we intend to issue assessment instructions to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of these final results of review, to liquidate shipments of subject merchandise entered, or withdrawn from warehouse, for consumption, on or after January 1, 2016, through December 31, 2016, at the *ad valorem* rates listed above.

Cash Deposit Instructions

In accordance with section 751(a)(1) of the Act, we intend to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 18, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

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II. Background

[2] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] *See* ''Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China; 2016,'' dated concurrently with this notice (Issues and Decision Memorandum) and hereby adopted by this notice.

[4] *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.

[5] *See* Appendix II.

[6] *See, e.g., Certain Pasta from Italy: Preliminary Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 18806, 18811 (April 13, 2010), unchanged in *Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 37386 (June 29, 2010).

[7] *See* 19 CFR 351.224(b).

III. List of Comments from Interested Parties
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1. Allocation Period
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XII. Recommendation
Appendix—Non-Selected Companies Under Review

Appendix II

Non-Selected Companies Under Review

1. Best Industries Ltd.
2. BC Tyre Group Limited
3. Crown International Corporation
4. Dongying Zhongyi Rubber Co., Ltd.
5. Hankook Tire China Co., Ltd.
6. Hong Kong Tiancheng Investment & Trading Co., Limited
7. Hongtyre Group Co.
8. Jiangsu Hankook Tire Co., Ltd.
9. Jiangsu Sanhe Aluminum
10. Kenda Rubber (China) Co., Ltd.
11. Koryo International Industrial Limited
12. Mayrun Tyre (Hong Kong) Limited
13. Qingdao Jinhaoyang International Co., Ltd.
14. Qingdao Nama Industrial Co., Ltd.
15. Qingdao Odyking Tyre Co., Ltd.
16. Roadclaw Tyre (Hong Kong) Limited
17. Shandong Anchi Tyres Co., Ltd.
18. Shandong Haohua Tire Co., Ltd.
19. Shandong Haolong Rubber Co., Ltd.
20. Shandong Hengyu Science & Technology Co., Ltd.
21. Shandong Linglong Tyre Co., Ltd.
22. Shandong Longyue Rubber Co., Ltd.
23. Shandong New Continent Tire Co., Ltd.
24. Shandong Province Sanli Tire
25. Shandong Province Sanli Tire Manufactured Co., Ltd.
26. Shandong Shuangwang Rubber Co., Ltd.
27. Shandong Wanda Boto Tyre Co., Ltd.
28. Shandong Yongsheng Rubber Group Co., Ltd.
29. Shouguang Firemax Tyre Co., Ltd.
30. The Yokohama Rubber Company, Ltd.
31. Tyrechamp Group Co., Limited
32. Winrun Tyre Co., Ltd.
33. Zhaoqing Junhong Co., Ltd.

[FR Doc. 2019–08347 Filed 4–24–19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG612

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Site Characterization Surveys off the Coast of North Carolina

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 Avangrid Renewables, LLC for authorization to take marine mammals incidental to high-resolution geophysical (HRG) survey investigations associated with marine site characterization activities off the coast of North Carolina in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0508) (the Lease Area) and the coastal waters off North Carolina and Virginia where one or more cable route corridors will be established. 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-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 May 28, 2019.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.pauline@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 received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act*. 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: Rob Pauline, 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/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable*. 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 issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be 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 such species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the monitoring and reporting of such takings must be set forth.

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 incidental harassment authorization) with respect to potential impacts on the human environment.

NMFS is preparing an Environmental Assessment (EA) to consider the environmental impacts associated with the issuance of the proposed IHA. NMFS' EA will be made available at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act*.

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 October 4, 2018, NMFS received a request from Avangrid for an IHA to take marine mammals incidental to HRG survey investigations off the coast of North Carolina in the OCS–A 0508 Lease Area and in the coastal waters of Virginia and North Carolina where one or more cable route corridors will be established to support the development of an offshore wind project. The application was deemed adequate and complete on February 21, 2019. Avangrid's request is for take of small numbers of nine species by Level B harassment only. Neither Avangrid nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The purpose of the marine site characterization survey is to support the siting, design, and deployment of up to three meteorological data buoy deployment areas and obtain a baseline assessment of seabed/sub-surface soil conditions in the Lease Area and cable route corridors to support the siting of a proposed wind farm. Underwater sound resulting from use of HRG equipment for site characterization purposes can have the potential to result in incidental take of marine mammals. The survey area extends along the coast from near the mouth of the Chesapeake Bay to Currituck, North Carolina. Up to 37 days of active HRG survey operations are planned and could take place at time during the one year authorization period. This take of marine mammals is anticipated to be in the form of harassment only; no serious injury or mortality is anticipated, nor is any proposed for authorization here.

Dates and Duration

HRG Surveys are anticipated to commence no earlier than June 1, 2019, and will last for approximately 37 days. This survey schedule is based on 24-hour operations and includes estimated weather down time. The proposed surveys are planned to take place during the summer months. The IHA would be effective for one year.

Specific Geographic Region

Avangrid's survey activities will occur in the approximately 122,317-acre Lease Area located approximately 31.3 nautical miles off the coast of Currituck, North Carolina, in Federal waters of the United States (see Figure 1 in Application). In addition, multiple cable route corridors will be surveyed within the area identified in Figure 1 in the Application. Each survey corridor is anticipated to be 30 to 70 nautical miles and extend from the lease area to landfall locations to be determined. For the purpose of this proposed IHA, the survey area is considered to be the Lease Area and cable route corridors. Water depths across the survey area are relatively shallow. Lease Area depths range from approximately 20 to 50 m (66 to 164 feet (ft)) while the cable route corridors will extend to shallow water close to landfall.

Detailed Description of Specific Activity

HRG surveys are employed to detect geohazards, archaeological resources, certain types of benthic communities, and to assess seafloor suitability for supporting structures such as platforms, pipelines, cables, and wind turbines. These surveys for renewable energy occur in shallow waters. HRG surveys typically use only electromechanical sources such as side-scan sonars; boomer, sparker, and chirp sub-bottom profilers; and multibeam depth sounders, some of which are expected to be beyond the functional hearing range of marine mammals or would be detectable only at very close range.[1]

Marine site characterization surveys will include the following HRG survey activities:

- Multibeam echosounder use to determine site bathymetry and elevations;
- Seafloor imaging (sidescan sonar survey) for seabed sediment classification purposes, to identify natural and man-made acoustic targets resting on the bottom as well as any anomalous features;
- Shallow penetration sub-bottom profiler (pinger/chirp) to map the near surface stratigraphy (top 0 to 5 m (0 to 16 ft) of soils below seabed);
- Medium penetration sub-bottom profiler (sparker) to map deeper subsurface stratigraphy as needed (soils down to 75 to 100 m (246 to 328 ft) below seabed);
- Magnetic intensity measurements for detecting local variations in regional magnetic field from geological strata and potential ferrous objects on and below the bottom; and
- Benthic Drop-down Video (DDV) and grab samples to inform and confirm geophysical interpretations and to provide further detail on areas of potential benthic and ecological interest.

Note that take of marine mammals is not associated with use of magnetic intensity measurement devices, DDV, or grab sample equipment.

A technical report conducted by the Naval Undersea Warfare Center (NUWC), through support from the Bureau of Ocean Energy Management (BOEM) and the United States Geological Survey, published measurements of the acoustic output from a variety of sources used during HRG surveys (Crocker and Fratantonio,

[1] HRG surveys are distinguishable from deep penetration seismic surveys, which occur in deeper offshore waters and are associated with oil and gas exploration. Seismic surveys are not used for renewable energy development. Deep penetration seismic airgun surveys are conducted by vessels towing an array of airguns that emit acoustic energy pulses into the seafloor, and which may occur over long durations and over large areas. In contrast with HRG surveys, airguns are considered a low-frequency source since most of its acoustic energy is radiated at frequencies below 200 Hz.

2016). The HRG test equipment were operated over a wide range of settings with different acoustic levels measured. As a conservative measure, the highest sound source levels and pulse duration for each piece of equipment were applied to the analysis herein. Representative equipment and source level characteristics are listed in Table 1. The exact make and model of the listed HRG equipment may vary depending on availability but will be equivalent to those described here.

TABLE 1—MEASURED SOURCE LEVELS OF REPRESENTATIVE HRG SURVEY EQUIPMENT

HRG system	Representative HRG survey equipment	Operating frequencies	Peak source level	RMS source level	Pulse duration (ms)	Beam width (degree)	Signal type
Subsea Positioning/ USBL.[1]	Sonardyne Ranger 2 USBL.	35–50 kHz	200 dB_{peak}	188 dB_{RMS}	16	180	FM Chirp.
Sidescan Sonar.	Klein 3900 Sidescan Sonar.	445 kHz/ 900 kHz	226 dB_{peak}	220 dB_{RMS}	0.016 to 0.100	1 to 2	Impulse.
Shallow penetration sub-bottom profiler.	EdgeTech 512i.	0.4 to 12 kHz	186 dB_{peak}	179 dB_{RMS}	1.8 to 65.8	51 to 80	FM Chirp.
Parametric Shallow penetration sub-bottom profiler.	Innomar parametric SES–2000 Standard.	85 to 115 kHz	243 dB_{peak}	236 dB_{RMS}	0.07 to 2	1	FM Chirp.
Medium penetration sub-bottom profiler.	SIG ELC 820 Sparker.	0.9 to 1.4 kHz	215 dB_{peak}	206 dB_{RMS}	0.8	[2] 30	Impulse.
Multibeam Echo Sounder.	Reson T20–P	200/300/400 kHz	227 dB_{peak}	221 dB_{RMS}	2 to 6	1.8 ±0.2°	Impulse.

1: Equipment information not provided in Crocker and Fratantonio, 2016. Information provided is based on manufacturer specifications.
2: A beamwidth of 30 degrees from horizontal is considered typical for electrode sparker technologies. Specific beamwidth information is not readily available from the equipment manufacturer.

Note that the operating frequencies of both the multibeam echo sounder and side-scan sonar occur outside the hearing range of marine mammals. Since there are no impacts to cetaceans associated with use of this equipment, these sources are not considered further in this document.

The survey activities will be supported by a vessel, or vessels, capable of maintaining course and a survey speed of approximately 4 nautical miles per hour (knots, 7 kilometers per hour (km/hr)) while transiting survey lines. Surveys will be conducted along tracklines spaced 150 m (98 ft) apart, with tie-lines spaced every 500 m (1640 ft). Several survey vessels may be used simultaneously, but it is more likely that only a single vessel would conduct surveys at any one time.

To minimize cost, the duration of survey activities, and the period of potential impact on marine species while surveying, Avangrid has proposed conducting continuous HRG survey operations 24 hours per day. Based on 24-hour operations, the estimated duration of the HRG survey activities would be approximately 37 days. Additional time (up to 30 days) may be required to obtain full multibeam coverage in shallow water areas, however the multibeam sensor operates at frequencies above the functional hearing ranges of marine mammals; therefore take of marine mammals is not expected as a result of multibeam-only survey activity, and multibeam-only survey activity is not analyzed further in this document.

The deployment of HRG survey equipment, including the use of sound-producing equipment operating below 200 kHz (*e.g.,* sub-bottom profilers), may have the potential to result in harassment of marine mammals. Based on the frequency ranges of the potential equipment to be used in support of the HRG survey activities; the ultra-short baseline (USBL) positioning system and the sub-bottom profilers (shallow and medium penetration) operate within the established marine mammal hearing ranges and have the potential to result in Level B harassment of marine mammals.

NMFS has previously issued IHAs for HRG surveys conducted in the Atlantic Ocean, off the east coast of the United States. Most of these have occurred in the coastal waters of southern New England, although NMFS recently issued an IHA for an HRG survey investigating unexploded ordnance (UXO) off the coast of Virginia as part of an offshore wind project (83 FR 39062, August 8, 2018). Marine mammal monitoring reports submitted after completion of HRG surveys indicated that authorized take numbers have never been exceeded.

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 2 lists species with expected potential for take in the survey area and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2018). 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 or serious injury 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' U.S. Atlantic SARs (*e.g.,* Hayes *et al.,* 2018). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2017 SARs (Hayes *et al.,* 2018) and draft 2018 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draftmarine-mammal-stock-assessment-reports*).

TABLE 2—MARINE MAMMAL SPECIES THAT MAY OCCUR NEAR THE SURVEY AREA

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 Balaenidae						
North Atlantic Right whale.	*Eubalaena glacialis.*	Western North Atlantic (WNA)	E/D; Y	451 (0; 445; 2017)	0.9	5.56
Family Balaenopteridae (rorquals)						
Humpback whale	*Megaptera novaeangliae.*	Gulf of Maine	-/-; N	896 (0; 896; 2012)	14.6	9.8
Fin whale	*Balaenoptera physalus.*	WNA	E/D; Y	1,618 (0.33; 1,234; 2011)	2.5	2.5
Sei whale	*Balaenoptera borealis.*	Nova Scotia	E/D; Y	357 (0.52; 236	0.5	0.6
Minke whale	*Balaenoptera acutorostrata.*	Canadian East Coast	-/-; N	2,591 (0.81; 1,425	14	7.5
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Short-finned pilot whale.	*Globicephala macrorhyn-. chus*	WNA	-/-; Y	21,515 (0.37; 15,913:2011)	159	192
Long-finned pilot whale.	*Globicephala melas.*	WNA	-/-; Y	5,636 (0.63; 3,464)	35	38
Bottlenose dolphin.	*Tursiops spp.*	WNA Offshore	-/-; N	77,532 (0.40; 56053; 2016)	561	39.4
		WNA Southern Migratory Coastal	-/-; Y	3,751 (0.060; 2,353; 2017)	23	0–12.3
Short beaked common dolphin.	*Delphinus delphis.*	WNA	-/-; N	70,184 (0.28; 55,690;2011)	557	406
Atlantic white-sided dolphin.	*Lagenorhynchus acutus.*	WNA	-/-; N	48,819 (0.61; 30,403; 2011)	304	30
Atlantic spotted dolphin.	*Stenella frontalis*	WNA	-/-: N	44,715 (0.43; 31,610; 2013)	316	0
Risso's dolphin ...	*Grampus griseus*	WNA	-/-; N	18,250 (0.5; 12,619; 2011)	126	49.7
Family Phocoenidae (porpoises)						
Harbor porpoise	*Phocoena phocoena.*	Gulf of Maine/Bay of Fundy	-/-; N	79,833 (0.32; 61,415; 2011)	706	255

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: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region/*. CV is 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's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

Three marine mammal species that are listed under the Endangered Species Act (ESA) may be present in the survey area: The North Atlantic right whale, fin whale, and sei whale. However, NMFS is not proposing authorized take of any of these species. The proposed authorization of take for 10 species (with 11 managed stocks) is described in the *Estimated Take* section. However, the temporal and/or spatial occurrence of Bryde's whale, blue whale and sperm whale is such that take is not expected to occur. While the BOEM Environmental Assessment (EA) for the North Carolina Wind Energy Areas (2015) indicates that Bryde's whales may be present during fall and winter, their presence in the survey area is very rare and unlikely during the summer (BOEM 2015). The blue whale is an occasional visitor along the northeast Atlantic coast. Sightings of blue whales off Cape Cod, Massachusetts, in summer and fall may represent the southern limit of the feeding range of the western North Atlantic stock that feeds primarily off the Canadian coast. The sperm whale occurs on the continental shelf edge, over the continental slope, and into mid-ocean regions in deeper waters than those in the project area. (NMFS 2015). Because the potential for the Bryde's whale, blue whale and sperm whale to occur within the survey area is unlikely, these species will not be described further. In addition, while strandings data exists for harbor and gray seals along the Mid-Atlantic coast south of New Jersey, their preference for colder, northern waters during the survey period makes their presence in the survey area unlikely during the summer and fall (Hayes *et al* 2018). Winter haulout sites for harbor seals have been identified within the Chesapeake Bay region and Outer Banks beaches, however the seals are only occasionally sited as far south as the Carolinas and are not likely to be present during spring and summer months during which survey activities are planned (Hayes *et al.* 2018). In addition, coastal Virginia and North Carolina represent the southern extent of the habitat range for gray seals, with few stranding records reported for the even more southern waters of North Carolina and sightings occurring only during winter months as far south as New Jersey (Waring *et al.* 2016). Therefore, these seal species will not be described further in this analysis.

North Atlantic Right Whale

The North Atlantic right whale was listed as a Federal endangered species in 1970. The right whale is a strongly migratory species, with some portion of the population moving annually between high-latitude feeding grounds and low latitude calving and breeding grounds. The present range of the western North Atlantic right whale population extends from the southeastern United States, which is utilized for wintering and calving by some individuals, to summer feeding and nursery grounds between New England and the Bay of Fundy and the Gulf of St. Lawrence (Kenney 2002; Waring *et al.* 2011). The winter distribution of much of the population that does not take part in seasonal migration is largely unknown, although offshore surveys have reported 1 to 13 detections annually in northeastern Florida and southeastern Georgia (Waring *et al.* 2013). Right whales have been observed in or near Virginia and North Carolina waters from October through December, as well as in February and March, which coincides with the migratory time frame for this species (Knowlton *et al.* 2002). A few events of right whale calving have been documented from shallow coastal areas and bays (Kenney 2002). Some evidence provided through acoustic monitoring suggests that not all individuals of the population participate in annual migrations, with a continuous presence of right whales occupying their entire habitat range throughout the year, particularly north of Cape Hatteras (Davis *et al.* 2017). However, an analysis of the composition and distribution of individual right whale sightings archived by the North Atlantic Right Whale Consortium from 1998 through 2015 suggests that very few whales would be present year-round. These data also recognize changes in population distribution throughout the right whale habitat range that could be due to environmental or anthropogenic effects, a response to short-term changes in the environment, or a longer-term shift in the right whale distribution cycle (Davis *et al.* 2017).

The proposed survey area is part of a migratory Biologically Important Area (BIA) for North Atlantic right whales; this important migratory area is comprised of the waters of the continental shelf offshore the East Coast of the United States and extends from Florida through Massachusetts. Additionally, NMFS' regulations at 50 CFR 224.105 impose vessel speed limits in designated Seasonal Management Areas (SMA) in nearshore waters of the Mid-Atlantic Bight. SMAs were developed to reduce the threat of collisions between ships and right whales around their migratory route and calving grounds. NMFS requires that all vessels 65 ft (19.8 m) or longer must travel at 10 knots or less within the right whale SMA from November 1 through April 30 when right whales are most likely to pass through these waters (NOAA 2010). A small section of the cable routing area overlaps spatially with the Chesapeake Bay SMA.

The western North Atlantic population demonstrated overall growth of 2.8 percent per year between 1990 and 2010 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). 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. However, in 2019 at least seven right whale calves have been identified (Savio 2019).

Elevated North Atlantic right whale mortalities have occurred since June 7, 2017. A total of 20 confirmed dead stranded whales (12 in Canada; 8 in the United States), have been documented to date. This event has been declared an Unusual Mortality Event (UME), with human interactions (*i.e.,* fishery-related entanglements and vessel strikes) identified as the most likely cause. More information is available online at: *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-north-atlantic-right-whale-unusual-mortality-event*.

Humpback Whale

Humpback whales are found worldwide in all oceans. In 1973, the

ESA listed humpbacks as endangered. NMFS recently evaluated the status of the species, and 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. The best estimate of population abundance for the West Indies DPS is 12,312 individuals, as described in the NMFS Status Review of the Humpback Whale under the Endangered Species Act (Bettridge *et al.,* 2015). This abundance estimate, for the West Indies breeding population, is more appropriate for use in reference to whales that may occur in the survey area than is the estimate given in Table 2, which is specific to the Gulf of Maine feeding population.

Since January 2016, elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida. The event has been declared a UME. Partial or full necropsy examinations have been conducted on approximately half of the 88 known cases. A portion of the whales have shown evidence of pre-mortem vessel strike; however, this finding is not consistent across all of the whales examined so 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 detailed information is available at*: https://www.fisheries.noaa.gov/national/marine-life-distress/2016-2018-humpback-whale-unusual-mortality-event-along-atlantic-coast#causes-of-the-humpback-whale-ume* (accessed February 25, 2019). Three previous UMEs involving humpback whales have occurred since 2000, in 2003, 2005, and 2006.

During winter, the majority of humpback whales from North Atlantic feeding areas mate and calve in the West Indies, where spatial and genetic mixing among feeding groups occurs, though significant numbers of animals are found in mid- and high-latitude regions at this time and some individuals have been sighted repeatedly within the same winter season, indicating that not all humpback whales migrate south every winter (Waring *et al.,* 2017). While migrating, 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.* 2013). Humpbacks typically occur within the Mid-Atlantic region during fall, winter, and spring months (Waring *et al.* 2012).

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.,* 2017). 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, though densities vary seasonally (Waring *et al.,* 2017). They are found in small groups of up to five individuals (Brueggeman *et al.,* 1987).

Present threats to fin whales are similar to other whale species, namely fishery entanglements and vessel strikes. Fin whales seem less likely to become entangled than other whale species. Glass *et al.* (2008) reported that between 2002 and 2006, fin whales belonging to the Gulf of Maine population were involved in only eight confirmed entanglements with fishery equipment. Furthermore, Nelson *et al.* (2007) reported that fin whales exhibited a low proportion of entanglements (eight reported events) during their 2001 to 2005 study along the western Atlantic. On the other hand, vessel strikes may be a more serious threat to fin whales. Eight and 10 confirmed vessel strikes with fin whales were reported by Glass *et al.* (2008) and Nelson *et al.* (2007), respectively. This level of incidence was similar to that exhibited by the other whales studied. Conversely, a study compiling whale/vessel strike reports from historical accounts, recent whale strandings, and anecdotal records by Laist *et al.* (2001) reported that of the 11 great whale species studied, fin whales were involved in collisions most frequently.

Fin whales are present in the Mid-Atlantic region during all four seasons, although sightings data indicate that they are more prevalent during winter, spring, and summer (Waring et al 2012). While fall is the season of lowest overall abundance off Virginia and North Carolina, they do not depart the area entirely.

Sei Whale

The sei whale is a widespread species in the world's temperate, subpolar, subtropical, and tropical marine waters. NOAA Fisheries considers sei whales occurring from the U.S. East Coast to Cape Breton, Nova Scotia, and east to 42° W as the ''Nova Scotia stock'' of sei whales (Waring *et al.* 2016; Hayes *et al.* 2018). Sei whales occur in deep water characteristic of the continental shelf edge throughout their range (Hain *et al.* 1985). They are often found in pairs (Schilling, 1992). In the Northwest Atlantic, it is speculated that the whales migrate from south of Cape Cod along the eastern Canadian coast in June and July, and return on a southward migration again in September and October (Waring *et al.* 2014; 2016). The sei whale is most common on Georges Bank and into the Gulf of Maine/Bay of Fundy region during spring and summer, primarily in deeper waters.

There is limited information on the stock identity of sei whales in the North Atlantic and insufficient data to determine trends of the Nova Scotian sei whale population (Hayes *et al.* 2018). A final recovery plan for the sei whale was published in 2011 (NOAA Fisheries 2011). Sei whale occurrence is relatively rare in the survey area.

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.,* 2017). This species generally occupies waters less than 100 m deep on the continental shelf (Waring *et al.,* 2017).

Since 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. As of September 30, 2018, partial or full necropsy examinations have been conducted on more than 60 percent of the 57 known cases. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease. These findings are not consistent across all of the whales examined, so more research is needed. As part of the UME investigation process, NOAA is assembling an independent team of scientists to coordinate with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample stranded whales, and determine the next steps for the investigation. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-minke-whale-unusual-mortality-event-along-atlantic-coast* (accessed February 25, 2019).

Pilot Whale

Both the long-finned and short-finned pilot whale could occur in the survey

area. However, the long-finned pilot whale is more generally found farther north in deeper waters along the edge of the continental shelf (a depth of 330 to 3,300 feet (100 to 1,000 meters). While long-finned pilot whales have occasionally been observed stranded as far south as South Carolina, long-finned and short-finned pilot whales tend to overlap spatially along the mid-Atlantic shelf break between New Jersey and the southern flank of Georges Bank (Payne and Heinemann 1993; Rone and Pace 2012). The latitudinal ranges of the two species remain uncertain, although south of Cape Hatteras, most pilot whale sightings are expected to be short-finned pilot whales, while north of ~42° N most pilot whale sightings are expected to be long-finned pilot whales (Hayes *et al.* 2018).

Bottlenose Dolphin

The bottlenose dolphin occurs in oceans and peripheral seas at both tropical and temperate latitudes. In North America, bottlenose dolphins are found in surface waters with temperatures ranging from 10 to 32° C (50 to 90 °F).

There are two distinct bottlenose dolphin morphotypes: Coastal and offshore. The coastal morphotype resides in waters typically less than 65.6 ft (20 m) deep, along the inner continental shelf (within 7.5 km (4.6 miles) of shore), around islands, and is continuously distributed south of Long Island, New York into the Gulf of Mexico. These coastal populations are subdivided into seven stocks based largely upon spatial distribution (Waring *et al.* 2016). Of these 7 coastal stocks, the Western North Atlantic Southern Migratory Coastal stock is common in the coastal continental shelf waters off the coast of Virginia and North Carolina (Waring *et al.* 2018). These animals often move into or reside in bays, estuaries, the lower reaches of rivers, and coastal waters. The Southern Migratory Coastal Stock is one of only two (the other being the Northern Migratory Coastal Stock) thought to make broad-scale, seasonal migrations in coastal waters of the western North Atlantic. The spatial distribution and migratory movements of the Southern Migratory Coastal Stock are poorly understood and have been defined based on movement data from satellite-tag telemetry and photo-ID studies, and stable isotope studies. The distribution of this stock is best described by satellite tag-telemetry data which provided evidence for a stock of dolphins migrating seasonally along the coast between North Carolina and northern Florida (Garrison *et al.* 2017b). Tag-telemetry data collected from two dolphins tagged in November 2004 just south of Cape Fear, North Carolina, suggested that, during October–December, this stock occupies waters of southern North Carolina (south of Cape Lookout) where it may overlap spatially with the Southern North Carolina Estuarine System (SNCES) Stock in coastal waters ≤3 km from shore. Based on the satellite telemetry data, during January–March, the Southern Migratory Coastal Stock appears to move as far south as northern Florida. During April–June, the stock moves back north to North Carolina past the tagging site to Cape Hatteras, North Carolina (Garrison *et al.* 2017b). During the warm water months of July–August, the stock is presumed to occupy coastal waters north of Cape Lookout, North Carolina, to Assateague, Virginia, including Chesapeake Bay.

The Southern Migratory Coastal stock may also overlap to some degree with the western North Atlantic Offshore stock of common bottlenose dolphins. A combined genetic and logistic regression analysis that incorporated depth, latitude, and distance from shore was used to model the probability that a particular common bottlenose dolphin group seen in coastal waters was of the coastal versus offshore morphotype (Garrison *et al.* 2017a). North of Cape Hatteras during summer months, there is strong separation between the coastal and offshore morphotypes (Kenney 1990; Garrison *et al.* 2017a), and the coastal morphotype is nearly completely absent in waters >20 m depth. South of Cape Hatteras, the regression analysis indicated that the coastal morphotype is most common in waters <20 m deep, but occurs at lower densities over the continental shelf, in waters >20 m deep, where it overlaps to some degree with the offshore morphotype. For the purposes of defining stock boundaries, estimating abundance, and identifying bycaught samples, the offshore boundary of the Southern Migratory Coastal Stock is defined as the 20-m isobath north of Cape Hatteras and the 200-m isobath south of Cape Hatteras. In summary, this stock is best delimited in warm water months, when it overlaps least with other stocks, as common bottlenose dolphins of the coastal morphotype that occupy coastal waters from the shoreline to 200 m depth from Cape Lookout to Cape Hatteras, North Carolina, and coastal waters 0–20 m in depth from Cape Hatteras to Assateague, Virginia, including Chesapeake Bay (Hayes *et al.* 2018).

The biggest threat to the population is bycatch because they are frequently caught in fishing gear, gillnets, purse seines, and shrimp trawls (Waring *et al.,* 2016). They have also been adversely impacted by pollution, habitat alteration, boat collisions, human disturbance, and are subject to bioaccumulation of toxins. Scientists have found a strong correlation between dolphins with elevated levels of PCBs and illness, indicating certain pollutants may weaken their immune system (ACSonline 2004).

Common Dolphin

The short-beaked common dolphin is found world-wide in temperate to subtropical seas. In the North Atlantic, short-beaked 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. Common dolphins have been noted to be associated with Gulf Stream features (CETAP 1982; Selzer and Payne 1988; Waring *et al.,* 1992). The species is less common south of Cape Hatteras, although schools have been reported as far south as the Georgia/South Carolina border (Hayes *et al.,* 2018).

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 100-m depth contour from central West Greenland to North Carolina (Waring *et al.,* 2017). 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. Infrequent Virginia and North Carolina observations appear to represent the southern extent of the species' range during the winter months (Hayes *et al.,* 2018).

Atlantic Spotted Dolphin

There are two species of spotted dolphin in the Atlantic Ocean, the Atlantic spotted dolphin (*Stenella frontalis*) and the pantropical spotted

dolphin (*S. attenuata*) (Perrin *et al.,* 1987).

The Atlantic spotted dolphin ranges from southern New England, south through the Gulf of Mexico and the Caribbean to Venezuela (Leatherwood *et al.,* 1976; Perrin *et al.,* 1994). The Atlantic spotted dolphin prefers tropical to warm temperate waters along the continental shelf 10 to 200 meters (33 to 650 feet) deep to slope waters greater than 500 meters (1640 feet) deep. They regularly occur in continental shelf waters south of Cape Hatteras and in continental shelf edge and continental slope waters north of this region (Payne *et al.,* 1984; Mullin and Fulling 2003). Pantropical spotted dolphin sightings during surveys in the Atlantic have been concentrated in the slope waters north of Cape Hatteras while in waters south of Cape Hatteras sightings are recorded over the Blake Plateau and in deeper offshore waters of the mid-Atlantic. (NMFS 2014). Given that pantropical spotted dolphins are found in deeper slope waters, it is likely that only Atlantic spotted dolphins, preferring shallower waters, would be found in the survey area.

Risso's Dolphins

Risso's dolphins are distributed worldwide in tropical and temperate seas and in the Northwest Atlantic occur from Florida to eastern Newfoundland. Off the northeastern U.S. coast, Risso's dolphins are distributed along the continental shelf edge from Cape Hatteras northward to Georges Bank during spring, summer, and autumn. In winter, the range is in the mid-Atlantic Bight and extends outward into oceanic waters. In general, the population occupies the mid-Atlantic continental shelf edge year round (Hayes *et al.,* 2018).

Harbor Porpoise

The harbor porpoise inhabits shallow, coastal waters, often found in bays, estuaries, and harbors. In the western Atlantic, they are found from Cape Hatteras north to Greenland. During summer (July to September), harbor porpoises are concentrated in the northern Gulf of Maine and southern Bay of Fundy region, generally in waters less than 150 m deep with a few sightings in the upper Bay of Fundy and on Georges Bank. During fall (October–December) and spring (April–June), harbor porpoises are widely dispersed from New Jersey to Maine, with lower densities farther north and south. They are seen from the coastline to deep waters (>1800 m) although the majority of the population is found over the continental shelf. During winter (January to March), intermediate densities of harbor porpoises can be found in waters off New Jersey to North Carolina, and lower densities are found in waters off New York to New Brunswick, Canada. There does not appear to be a temporally coordinated migration or a specific migratory route to and from the Bay of Fundy region. However, during the fall, several satellite-tagged harbor porpoises did favor the waters around the 92-m isobaths (Hayes *et al.,* 2018)

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 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. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera Kogia and Cephalorhynchus; including two members of the genus Lagenorhynchus, on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Twelve marine mammal species, all cetaceans, have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 2. Of these cetacean species, 5 are classified as low-frequency cetaceans (*i.e.,* all mysticete species), 6 are classified as mid-frequency cetaceans (*i.e.,* all delphinid species), and 1 is classified as a high-frequency cetacean (*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. 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.

Background on Sound

Sound is a physical phenomenon consisting of minute vibrations that travel through a medium, such as air or water, and is generally characterized by several variables. Frequency describes the sound's pitch and is measured in Hz or kHz, while sound level describes the sound's intensity and is measured in dB. Sound level increases or decreases exponentially with each dB of change. The logarithmic nature of the scale means that each 10-dB increase is a 10-fold increase in acoustic power (and a 20-dB increase is then a 100-fold increase in power). A 10-fold increase in acoustic power does not mean that the sound is perceived as being 10 times louder, however. Sound levels are compared to a reference sound pressure (micro-Pascal) to identify the medium. For air and water, these reference

pressures are ''re: 20 micro pascals (μPa)'' and ''re: 1 μPa,'' respectively. Root mean square (RMS) is the quadratic mean sound pressure over the duration of an impulse. RMS is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1975). RMS 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. 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 rather than by peak pressures.

Acoustic Impacts

HRG survey equipment use during the geophysical surveys may temporarily impact marine mammals in the area due to elevated in-water sound levels. Marine mammals are continually exposed to many sources of sound. Naturally occurring sounds such as lightning, rain, sub-sea earthquakes, and biological sounds (*e.g.,* snapping shrimp, whale songs) are widespread throughout the world's oceans. Marine mammals produce sounds in various contexts and use sound for various biological functions including, but not limited to: (1) Social interactions; (2) foraging; (3) orientation; and (4) predator detection. Interference with producing or receiving these sounds may result in adverse impacts. Audible distance, or received levels of sound depend on the nature of the sound source, ambient noise conditions, and the sensitivity of the receptor to the sound (Richardson *et al.,* 1995). Type and significance of marine mammal reactions to sound are likely dependent on a variety of factors including, but not limited to, (1) the behavioral state of the animal (*e.g.,* feeding, traveling, etc.); (2) frequency of the sound; (3) distance between the animal and the source; and (4) the level of the sound relative to ambient conditions (Southall *et al.,* 2007).

When sound travels (propagates) from its source, its loudness decreases as the distance traveled by the sound increases. Thus, the loudness of a sound at its source is higher than the loudness of that same sound a kilometer away. Acousticians often refer to the loudness of a sound at its source (typically referenced to one meter from the source) as the source level and the loudness of sound elsewhere as the received level (*i.e.,* typically the receiver). For example, a humpback whale 3 km from a device that has a source level of 230 dB may only be exposed to sound that is 160 dB loud, depending on how the sound travels through water (*e.g.,* spherical spreading (6 dB reduction with doubling of distance) was used in this example) and assuming no other sources of propagation loss (see below). As a result, it is important to understand the difference between source levels and received levels when discussing the loudness of sound in the ocean or its impacts on the marine environment.

As sound travels from a source, its propagation in water is influenced by various physical characteristics, including water temperature, depth, salinity, and surface and bottom properties that cause refraction, reflection, absorption, and scattering of sound waves. Oceans are not homogeneous and the contribution of each of these individual factors is extremely complex and interrelated. The physical characteristics that determine the sound's speed through the water will change with depth, season, geographic location, and with time of day (as a result, in actual active sonar operations, crews will measure oceanic conditions, such as sea water temperature and depth, to calibrate models that determine the path the sonar signal will take as it travels through the ocean and how strong the sound signal will be at a given range along a particular transmission path). As sound travels through the ocean, the intensity associated with the wavefront diminishes, or attenuates. This decrease in intensity is referred to as propagation loss, also commonly called transmission loss.

Hearing Impairment

Marine mammals may experience temporary or permanent hearing impairment when exposed to loud sounds. Hearing impairment is classified by temporary threshold shift (TTS) and permanent threshold shift (PTS). There are no empirical data for onset of PTS in any marine mammal; therefore, PTS-onset must be estimated from TTS-onset measurements and from the rate of TTS growth with increasing exposure levels above the level eliciting TTS-onset. PTS is considered auditory injury (Southall *et al.,* 2007) and occurs in a specific frequency range and amount. Irreparable damage to the inner or outer cochlear hair cells may cause PTS; however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.,* 2007). Given the higher level of sound and/or longer durations of exposure necessary to cause PTS as compared with TTS, and the small zone within which sound levels would exceed criteria for onset of PTS, it is unlikely that PTS would occur during the proposed HRG surveys.

Temporary Threshold Shift

TTS is the mildest form of hearing impairment that can occur during exposure to a loud sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. At least in terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days, can be limited to a particular frequency range, and can occur to varying degrees (*i.e.,* a loss of a certain number of dBs of sensitivity). For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the noise ends.

Marine mammal hearing plays a critical role in communication with conspecifics and in interpretation of environmental cues for purposes such as predator avoidance and prey capture. 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. 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 animals 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 a time when communication is critical for successful mother/calf interactions could have more serious impacts if it were in the same frequency band as the necessary vocalizations and of a severity such that it impeded communication. The fact that animals exposed to levels and durations of sound that would be expected to result in this physiological response would also be expected to have behavioral responses of a comparatively more severe or sustained nature is also notable and potentially of more importance than the simple existence of a TTS.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale, harbor porpoise, and Yangtze finless porpoise) exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band

noise) in laboratory settings (*e.g.,* Finneran *et al.,* 2002 and 2010; Nachtigall *et al.,* 2004; Lucke *et al.,* 2009; Mooney *et al.,* 2009; Popov *et al.,* 2011; Finneran and Schlundt, 2010). In general, harbor porpoises (Lucke *et al.,* 2009; Kastelein *et al.,* 2012b) have a lower TTS onset than other measured cetacean species. However, even for these animals, which are better able to hear higher frequencies and may be more sensitive to higher frequencies, exposures on the order of approximately 170 dB_{RMS} or higher for brief transient signals are likely required for even temporary (recoverable) changes in hearing sensitivity that would likely not be categorized as physiologically damaging (Lucke *et al.,* 2009). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see NMFS (2018), Southall *et al.* (2019), Finneran and Jenkins (2012), and Finneran (2015).

Scientific literature highlights the inherent complexity of predicting TTS onset in marine mammals, as well as the importance of considering exposure duration when assessing potential impacts (Mooney *et al.,* 2009a, 2009b; Kastak *et al.,* 2007). Generally, with sound exposures of equal energy, quieter sounds (lower sound pressure level (SPL)) of longer duration were found to induce TTS onset more than louder sounds (higher SPL) of shorter duration (more similar to sub-bottom profilers). For intermittent sounds, less threshold shift will occur than from a continuous exposure with the same energy (some recovery will occur between intermittent exposures) (Kryter *et al.,* 1966; Ward, 1997). For sound exposures at or somewhat above the TTS-onset threshold, hearing sensitivity recovers rapidly after exposure to the sound ends; intermittent exposures recover faster in comparison with continuous exposures of the same duration (Finneran *et al.,* 2010). NMFS considers TTS as Level B harassment that is mediated by physiological effects on the auditory system; however, NMFS does not consider TTS-onset to be the lowest level at which Level B harassment may occur.

Marine mammals in the survey area during the HRG survey are unlikely to incur TTS hearing impairment due to the characteristics of the sound sources, which include low source levels (208 to 221 dB re 1 µPa-m) and generally very short pulses and duration of the sound. Even for high-frequency cetacean species (*e.g.,* harbor porpoises), which may have increased sensitivity to TTS (Lucke *et al.,* 2009; Kastelein *et al.,* 2012b), 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) (Mooney *et al.,* 2009a; Finneran *et al.,* 2010). Moreover, most marine mammals would be more likely to 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 temporary threshold shift 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 the sub-bottom profiler and other HRG survey equipment makes it unlikely that an animal would be exposed more than briefly during the passage of the vessel. Boebel *et al.* (2005) concluded similarly for single and multibeam echosounders, and more recently, Lurton (2016) conducted a modeling exercise and concluded similarly that likely potential for acoustic injury from these types of systems is discountable, but that behavioral response cannot be ruled out. Animals may avoid the area around the survey vessels, thereby reducing exposure. Any disturbance to marine mammals is likely to be in the form of temporary avoidance or alteration of opportunistic foraging behavior near the survey location.

Masking

Masking is the obscuring of sounds of interest to an animal by other sounds, typically at similar frequencies. Marine mammals are highly dependent on sound, and their ability to recognize sound signals amid other sound is important in communication and detection of both predators and prey (Tyack, 2000). Background ambient sound may interfere with or mask the ability of an animal to detect a sound signal even when that signal is above its absolute hearing threshold. Even in the absence of anthropogenic sound, the marine environment is often loud. Natural ambient sound includes contributions from wind, waves, precipitation, other animals, and (at frequencies above 30 kHz) thermal sound resulting from molecular agitation (Richardson *et al.,* 1995).

Background sound may also include anthropogenic sound, and masking of natural sounds can result when human activities produce high levels of background sound. Conversely, if the background level of underwater sound is high (*e.g.,* on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. Ambient sound is highly variable on continental shelves (Thompson, 1965; Myrberg, 1978; Desharnais *et al.,* 1999). This results in a high degree of variability in the range at which marine mammals can detect anthropogenic sounds.

Although masking is a phenomenon which may occur naturally, the introduction of loud anthropogenic sounds into the marine environment at frequencies important to marine mammals increases the severity and frequency of occurrence of masking. For example, if a baleen whale is exposed to continuous low-frequency sound from an industrial source, this would reduce the size of the area around that whale within which it can hear the calls of another whale. The components of background noise that are similar in frequency to the signal in question primarily determine the degree of masking of that signal. In general, little is known about the degree to which marine mammals rely upon detection of sounds from conspecifics, predators, prey, or other natural sources. In the absence of specific information about the importance of detecting these natural sounds, it is not possible to predict the impact of masking on marine mammals (Richardson *et al.,* 1995). In general, masking effects are expected to be less severe when sounds are transient than when they are continuous. Masking is typically of greater concern for those marine mammals that utilize low-frequency communications, such as baleen whales, because of how far low-frequency sounds propagate.

Marine mammal communications would not likely be masked appreciably by the sub-bottom profiler signals given the directionality of the signal and the brief period when an individual mammal is likely to be within its beam.

Non-Auditory Physical Effects (Stress)

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 or the hypothalamus-pituitary-interrenal axis in fish and some reptiles). 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), altered metabolism (Elasser *et al.,* 2000), 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 equated with stress for many years.

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. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose a risk to the animal's welfare. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other biotic function, which impairs those functions that experience the diversion. For example, when mounting a stress response diverts energy away from growth in young animals, those animals may experience stunted growth. When mounting a stress response diverts energy from a fetus, an animal's reproductive success and its fitness will suffer. In these cases, the animals will have entered a pre-pathological or pathological state which is called ''distress'' (Seyle, 1950) or ''allostatic loading'' (McEwen and Wingfield, 2003). This pathological state will last until the animal replenishes its biotic reserves sufficient to restore normal function. Note that these examples involved a long-term (days or weeks) stress response exposure to stimuli.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses have also been documented fairly well through controlled experiments; because this physiology exists in every vertebrate that has been studied, it is not surprising that stress responses and their costs have been documented in both laboratory and free-living animals (for examples see, Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005; Reneerkens *et al.,* 2002; Thompson and Hamer, 2000). Information has also been collected on the physiological responses of marine mammals to exposure to anthropogenic sounds (Fair and Becker, 2000; Romano *et al.,* 2002). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. In a conceptual model developed by the Population Consequences of Acoustic Disturbance (PCAD) working group, serum hormones were identified as possible indicators of behavioral effects that are translated into altered rates of reproduction and mortality (NRC 2005).

Studies of other marine animals and terrestrial animals would also lead us to expect some marine mammals to experience physiological stress responses and, perhaps, physiological responses that would be classified as ''distress'' upon exposure to high frequency, mid-frequency and low-frequency sounds. For example, Jansen (1998) reported on the relationship between acoustic exposures and physiological responses that are indicative of stress responses in humans (for example, elevated respiration and increased heart rates). Jones (1998) reported on reductions in human performance when faced with acute, repetitive exposures to acoustic disturbance. Trimper *et al.* (1998) reported on the physiological stress responses of osprey to low-level aircraft noise while Krausman *et al.* (2004) reported on the auditory and physiology stress responses of endangered Sonoran pronghorn to military overflights. Smith *et al.* (2004a, 2004b), for example, identified noise-induced physiological transient stress responses in hearing-specialist fish (*i.e.,* goldfish) that accompanied short- and long-term hearing losses. Welch and Welch (1970) reported physiological and behavioral stress responses that accompanied damage to the inner ears of fish and several mammals.

Hearing is one of the primary senses marine mammals use to gather information about their environment and to communicate with conspecifics. Although empirical information on the effect of sensory impairment (TTS, PTS, and acoustic masking) on marine mammals remains limited, it seems reasonable to assume that reducing an animal's ability to gather information about its environment and to communicate with other members of its species would be stressful for animals that use hearing as their primary sensory mechanism. Therefore, we assume that acoustic exposures sufficient to trigger onset PTS or TTS would be accompanied by physiological stress responses because terrestrial animals exhibit those responses under similar conditions (NRC, 2003). More importantly, marine mammals might experience stress responses at received levels lower than those necessary to trigger onset TTS. Based on empirical studies of the time required to recover from stress responses (Moberg, 2000), we also assume that stress responses are likely to persist beyond the time interval required for animals to recover from TTS and might result in pathological and pre-pathological states that would be as significant as behavioral responses to TTS. NMFS does not expect that the generally short-term, intermittent, and transitory HRG surveys would create conditions of long-term, continuous noise and chronic acoustic exposure

leading to long-term physiological stress responses in marine mammals.

Behavioral Disturbance

Behavioral responses to sound are highly variable and context-specific. An animal's perception of and response to (in both nature and magnitude) an acoustic event can be influenced by prior experience, perceived proximity, bearing of the sound, familiarity of the sound, etc. (Southall *et al.,* 2007; DeRuiter *et al.,* 2013a and 2013b). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007).

Southall *et al.* (2007) reports the results of the efforts of a panel of experts in acoustic research from behavioral, physiological, and physical disciplines that convened and reviewed the available literature on marine mammal hearing and physiological and behavioral responses to human-made sound with the goal of proposing exposure criteria for certain effects. This peer-reviewed compilation of literature is very valuable, though Southall *et al.* (2007) note that not all data are equal, some have poor statistical power, insufficient controls, and/or limited information on received levels, background noise, and other potentially important contextual variables—such data were reviewed and sometimes used for qualitative illustration but were not included in the quantitative analysis for the criteria recommendations. All of the studies considered, however, contain an estimate of the received sound level when the animal exhibited the indicated response.

Studies that address responses of low-frequency cetaceans to sounds include data gathered in the field and related to several types of sound sources, including: vessel noise, drilling and machinery playback, low-frequency M-sequences (sine wave with multiple phase reversals) playback, tactical low-frequency active sonar playback, drill ships, and non-pulse playbacks. These studies generally indicate no (or very limited) responses to received levels in the 90 to 120 dB re: 1μPa range and an increasing likelihood of avoidance and other behavioral effects in the 120 to 160 dB range. As mentioned earlier, though, contextual variables play a very important role in the reported responses and the severity of effects do not increase linearly with received levels. Also, few of the laboratory or field datasets had common conditions, behavioral contexts, or sound sources, so it is not surprising that responses differ.

The studies that address responses of mid-frequency cetaceans to sounds include data gathered both in the field and the laboratory and related to several different sound sources, including: pingers, drilling playbacks, ship and ice-breaking noise, vessel noise, acoustic harassment devices (AHDs), acoustic deterrent devices (ADDs), mid-frequency active sonar, and non-pulse bands and tones. Southall *et al.* (2007) were unable to come to a clear conclusion regarding the results of these studies. In some cases animals in the field showed significant responses to received levels between 90 and 120 dB, while in other cases these responses were not seen in the 120 to 150 dB range. The disparity in results was likely due to contextual variation and the differences between the results in the field and laboratory data (animals typically responded at lower levels in the field). The studies that address the responses of mid-frequency cetaceans to impulse sounds include data gathered both in the field and the laboratory and related to several different sound sources, including: small explosives, airgun arrays, pulse sequences, and natural and artificial pulses. The data show no clear indication of increasing probability and severity of response with increasing received level. Behavioral responses seem to vary depending on species and stimuli.

The studies that address responses of high-frequency cetaceans to sounds include data gathered both in the field and the laboratory and related to several different sound sources, including: Pingers, AHDs, and various laboratory non-pulse sounds. All of these data were collected from harbor porpoises.

Marine mammals are likely to avoid the HRG survey activity, especially harbor porpoises. However, because the sub-bottom profilers and other HRG survey equipment operate from a moving vessel, and the assumed behavioral harassment distance is small (see *Estimated Take*), the area and time that this equipment would be affecting a given location is very small. Further, once an area has been surveyed, it is not likely that it will be surveyed again, therefore reducing the likelihood of repeated HRG-related impacts within the survey area.

We have also considered the potential for severe behavioral responses such as stranding and associated indirect injury or mortality from Avangrid's use of HRG survey equipment, on the basis of a 2008 mass stranding of approximately one hundred melon-headed whales in a Madagascar lagoon system. An investigation of the event indicated that use of a high-frequency mapping system (12-kHz multibeam echosounder) was the most plausible and likely initial behavioral trigger of the event, while providing the caveat that there is no unequivocal and easily identifiable single cause (Southall *et al.,* 2013). The investigatory panel's conclusion was based on (1) very close temporal and spatial association and directed movement of the survey with the stranding event; (2) the unusual nature of such an event coupled with previously documented apparent behavioral sensitivity of the species to other sound types (Southall *et al.,* 2006; Brownell *et al.,* 2009); and (3) the fact that all other possible factors considered were determined to be unlikely causes. Specifically, regarding survey patterns prior to the event and in relation to bathymetry, the vessel transited in a north-south direction on the shelf break parallel to the shore, ensonifying large areas of deep-water habitat prior to operating intermittently in a concentrated area offshore from the stranding site; this may have trapped the animals between the sound source and the shore, thus driving them towards the lagoon system. The investigatory panel systematically excluded or deemed highly unlikely nearly all potential reasons for these animals leaving their typical pelagic habitat for an area extremely atypical for the species (*i.e.,* a shallow lagoon system). Notably, this was the first time that such a system has been associated with a stranding event. The panel also noted several site- and situation-specific secondary factors that may have contributed to the avoidance responses that led to the eventual entrapment and mortality of the whales. Specifically, shoreward-directed surface currents and elevated chlorophyll levels in the area preceding the event may have played a role (Southall *et al.,* 2013).

The report also notes that prior use of a similar system in the general area may have sensitized the animals and also concluded that, for odontocete cetaceans that hear well in higher frequency ranges where ambient noise is typically quite low, high-power active sonars operating in this range may be more easily audible and have potential effects over larger areas than low frequency systems that have more typically been considered in terms of anthropogenic noise impacts. It is,

however, important to note that the relatively lower output frequency, higher output power, and complex nature of the system implicated in this event, in context of the other factors noted here, likely produced a fairly unusual set of circumstances that indicate that such events would likely remain rare and are not necessarily relevant to use of lower-power, higher-frequency systems more commonly used for HRG survey applications. The risk of similar events recurring may be very low, given the extensive use of active acoustic systems used for scientific and navigational purposes worldwide on a daily basis and the lack of direct evidence of such responses previously reported.

Tolerance

Numerous studies have shown that underwater sounds from industrial activities are often readily detectable by marine mammals in the water at distances of many kilometers. However, other studies have shown that marine mammals at distances more than a few kilometers away often show no apparent response to industrial activities of various types (Miller *et al.,* 2005). This is often true even in cases when the sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales and toothed whales have been shown to react behaviorally to underwater sound from sources such as airgun pulses or vessels under some conditions, at other times, mammals of all three types have shown no overt reactions (*e.g.,* Malme *et al.,* 1986; Richardson *et al.,* 1995; Madsen and Mohl, 2000; Croll *et al.,* 2001; Jacobs and Terhune, 2002; Madsen *et al.,* 2002; Miller *et al.,* 2005). Due to the relatively high vessel traffic in the survey area it is possible that marine mammals are habituated to noise from project vessels in the area.

Vessel Strike

Ship strikes of marine mammals can cause major wounds, which may lead to the death of the animal. An animal at the surface could be struck directly by a vessel, a surfacing animal could hit the bottom of a vessel, or a vessel's propeller could injure an animal just below the surface. The severity of injuries typically depends on the size and speed of the vessel (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007).

The most vulnerable marine mammals are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale). In addition, some baleen whales, such as the North Atlantic right whale, seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slow moving whales. Smaller marine mammals (*e.g.,* bottlenose dolphin) move quickly through the water column and are often seen riding the bow wave of large ships. Marine mammal responses to vessels may include avoidance and changes in dive pattern (NRC, 2003).

An examination of all known ship strikes from all shipping sources (civilian and military) indicates vessel speed is a principal factor in whether a vessel strike results in death (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Jensen and Silber, 2003; Vanderlaan and Taggart, 2007). In assessing records with known vessel speeds, Laist *et al.* (2001) found a direct relationship between the occurrence of a whale strike and the speed of the vessel involved in the collision. The authors concluded that most deaths occurred when a vessel was traveling in excess of 24.1 km/h (14.9 mph; 13 knots). Given the slow vessel speeds and predictable course necessary for data acquisition, ship strike is unlikely to occur during the geophysical surveys. Marine mammals would be able to easily avoid vessels and are likely already habituated to the presence of numerous vessels in the area. Further, Avangrid will implement measures (*e.g.,* vessel speed restrictions and separation distances; see *Proposed Mitigation Measures*) to reduce the risk of a vessel strike to marine mammal species in the survey area.

Effects on Marine Mammal Habitat

There are no feeding areas, rookeries, or mating grounds known to be biologically important to marine mammals within the proposed project area with the exception of a migratory BIA for right whales which was described previously. There is also no designated critical habitat for any ESA-listed marine mammals. NMFS' regulations at 50 CFR 224.105 designated the nearshore waters of the Mid-Atlantic Bight as the Mid-Atlantic SMA for right whales in 2008. Mandatory vessel speed restrictions are in place in that SMA from November 1 through April 30 to reduce the threat of collisions between ships and right whales around their migratory route and calving grounds.

We are not aware of any available literature on impacts to marine mammal prey species from HRG survey equipment. However, because the HRG survey equipment introduces noise to the marine environment, there is the potential for avoidance of the area around the HRG survey activities by marine mammal prey species. Any avoidance of the area on the part of marine mammal prey species would be expected to be short term and temporary. Because of the temporary nature of the disturbance, the availability of similar habitat and resources (*e.g.,* prey species) in the surrounding area, and the lack of important or unique marine mammal habitat, 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).

As described previously, no 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) and the number of days of activities. We note that while these basic factors can contribute to a 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

Using the best available science, NMFS has developed 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 for non-explosive sources—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). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 160 dB re 1 µPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Avangrid's proposed activity includes the use of impulsive and/or intermittent sources (HRG equipment) and, therefore, the 160 dB re 1 µPa (rms) 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) (NMFS, 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). Avangrid's proposed activity includes the use of impulsive sources (medium penetration sub-bottom profiler) and non-impulsive sources (shallow penetration sub-bottom profiler).

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 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

	PTS onset acoustic thresholds * (received level)	
Hearing group	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 (FF) 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:* $L_{E,OW,24h}$: 201 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.

Previously we explained that auditory injury of marine mammals is unlikely given the higher level of sound and/or longer durations of exposure necessary to cause PTS and the small zone within which sound levels would exceed criteria for onset of PTS. The information provided in Tables 4 and 5 support this position and demonstrate that the proposed mitigation measures are based on a highly conservative evaluation of potential acoustic impacts.

When the NMFS Technical Guidance was first published in 2016, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available. NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For mobile sources, including the HRG survey equipment, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed. Note however, that use of the spreadsheet is generally not appropriate for use in assessing potential for Level A harassment for very highly directional sources, such as the Innomar SES–2000, for reasons explained below. Inputs used in the User Spreadsheet and the resulting isopleths are reported below.

TABLE 4—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING HARASSMENT ISOPLETHS

Spreadsheet tab used	USBL	Shallow penetration SBP	Medium penetration SBP
	D: Mobile source: Non-impulsive, intermittent	D: Mobile source: Non-impulsive, intermittent	F: Mobile source: Impulsive, intermittent
Source Level (dB)	188 RMS SPL	179 RMS SPL	206 RMS SPL
Weighting Factor Adjustment (kHz)	26.5	2.6	1.4
Source Velocity (m/s)	2.058	2.058	2.058
Pulse Duration (seconds)	0.016	0.0658	0.008
1/Repetition rate – (seconds)	0.33	0.25	0.25
Source Level (PK SPL)	.....	.....	215
Propagation (xLogR)	20	20	20

Note that the Innomar SES–2000 is a specialized type of HRG sub-bottom profiler that uses the principle of ''parametric'' or ''nonlinear'' acoustics to generate short narrow-beam sound pulses. As no field data currently exists for the Innomar sub-bottom profiler acoustic modeling was completed using a version of the U.S. Naval Research Laboratory's Range-dependent Acoustic Model (RAM) and BELLHOP Gaussian beam ray-trace propagation model (Porter and Liu 1994). Calculations of the ensonified area are conservative due to the directionality of the sound sources. Due to the short sound pulses and the highly directional sound pulse transmission (1° beamwidth) of parametric sub-bottom profilers, the volume of area affected is much lower than using conventional (linear) acoustics devices such as sparker and chirp systems. Level A harassment zones of less than 5 meters (Table 5) for HF cetaceans were calculated for this HRG equipment in the proposed survey area while Level B harassment isopleths were found to range from 120 to 135 meters (Table 6).

TABLE 5—MAXIMUM DISTANCES TO LEVEL A HARASSMENT THRESHOLDS BY EQUIPMENT CATEGORY

Representative HRG survey equipment	Marine mammal group	PTS onset	Lateral distance (m)
USBL/GAPS Positioning Systems			
Sonardyne Ranger 2 USBL HPT 5/7000	LF cetaceans	199 dB SEL_{cum}.	
	MF cetaceans	198 dB SEL_{cum}.	
	HF cetaceans	173 dB SEL_{cum}	3
Shallow Sub-bottom Profiler			
Edgetech 512i	LF cetaceans	199 dB SEL_{cum}.	
	MF cetaceans	198 dB SEL_{cum}.	
	HF cetaceans	173 dB SEL_{cum}.	
Shallow Parametric Sub-bottom Profiler			
Innomar SES–2000 Standard Parametric Sub-bottom Profiler.	LF cetaceans	199 dB SEL_{cum}	N/A
	MF cetaceans	198 dB SEL_{cum}.	
	HF cetaceans	173 dB SEL_{cum}	<5
Medium Penetration Sub-bottom Profiler			
SIG ELC 820 Sparker	LF cetaceans	219 dBpeak, 183 dB SEL_{cum}	—, 10
	MF cetaceans	230 dBpeak, 185 dB SEL_{cum}	—,—
	HF cetaceans	202 dBpeak, 155 dB SEL_{cum}	5, 4

Notes:
The peak SPL criterion is un-weighted (*i.e.,* flat weighted), whereas the cumulative SEL criterion is weighted for the given marine mammal functional hearing group.
The calculated sound levels and results are based on NMFS Technical Guidance's companion User Spreadsheet except as indicated.
— indicates that no injury was predicted for the given HRG equipment noise profile.
N/A indicates not applicable as the HRG sound source operates outside the effective marine mammal hearing range

Distances to Level B harassment noise thresholds were calculated using the conservative practical spreading model (transmission loss (TL) equation: $TL = 15\log_{10}r$), with the exception of the Innomar SES–2000 described previously. The Sig ELC 820 Sparker was calculated to have the largest Level B harassment isopleth of 200 m (656.2 ft). To account for some of the potential variation of operating conditions, the maximum distance of 200 m to the harassment thresholds is used to determine estimated exposure. The 200 m distance to the medium penetration sub-bottom profiler represents the largest distance and is likely a very conservative estimate based on sound

source field verification assessments of similar sparker electrode equipment.

The 200 m distance to the medium penetration sub-bottom profiler represents the largest distance and is likely a very conservative estimate based on sound source field verification assessments of similar sparker electrode equipment.

TABLE 6—DISTANCES TO LEVEL B HARASSMENT THRESHOLDS

[160 dB_{RMS}]

Survey equipment	Marine mammal level B harassment 160 dB_{RMS} re 1 µPa (m)
USBL	
Sonardyne Ranger 2 USBL	25
Shallow penetration sub-bottom profiler	
EdgeTech 512i	10
Innomar parametric SES–2000 Standard	120–135
Medium penetration sub-bottom profiler	
SIG ELC 820 Sparker	200

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. The data used as the basis for estimating cetacean density (''D'') for the survey area are sightings per unit effort (SPUE) derived by Duke University (Roberts *et al.* 2016a), updated with new modeling results (Roberts *et al.* 2016b; 2017; 2018). SPUE (or, the relative abundance of species) is derived by using a measure of survey effort and number of individual cetaceans sighted. SPUE allows for comparison between discrete units of time (*i.e.* seasons) and space within a project area (Shoop and Kenney, 1992). The Duke University (Roberts *et al.* 2016) cetacean density data represent models derived from aggregating line-transect surveys conducted over 23 years by five institutions (NOAA NMFS Northeast Fisheries Science Center, New Jersey Department of Environmental Protection, NOAA NMFS Southeast Fisheries Science Center, University of North Carolina Wilmington, and Virginia Aquarium & Marine Science Center). Model versions discussed in Roberts et al. (2016a) are freely available online at the Ocean Biogeographic Information System Spatial Ecological Analysis of Megavertebrate Populations (OBISSEAMAP) repository. Monthly mean density values within the survey area were averaged by season (Winter (December, January, February), Spring (March, April, May), Summer (June, July, August), Fall (September, October, November)) to provide seasonal density estimates for those taxa for which monthly model results are available. The highest seasonal density estimates during the duration of the proposed survey were used to estimate take (*i.e.,* summer or fall). (2016b; 2017; 2018).

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 harassment thresholds are calculated, as described above. Those distances are then used to calculate the area(s) around the HRG survey equipment predicted to be ensonified to sound levels that exceed harassment thresholds. The area estimated to be ensonified to relevant thresholds in a single day of the survey is then calculated, based on areas predicted to be ensonified around the HRG survey equipment and the estimated survey vessel trackline distance traveled per day.

The survey activities that have the potential to cause Level B harassment (160 dB_{RMS} re 1 µPa) are listed in Table 6. Based on the results of this assessment, the furthest distance to the Level B harassment criteria is 200 m from the use of the SIG ELC 820 Sparker. As a conservative measure to account for some of the potential variation of operating conditions, the maximum distance of 200 m to the Level B harassment isopleth for the SIG ELC 820 Sparker is used to determine estimated exposure for the entire HRG survey.

The estimated distance of the daily vessel trackline was determined using the estimated average speed of the vessel (4 knots) and the 24-hour operational period. Using the maximum distance to the Level B harassment threshold of 200 m (656 ft) and estimated daily vessel track of approximately 177.8 km (110.5 mi), estimates of take by survey equipment has been based on an ensonified area around the survey equipment of 71.2 km^2 (27.5 mi^2) per day over a projected survey period for each survey segment as shown in Table 7.

TABLE 7—SURVEY SEGMENT DISTANCES AND LEVEL B HARASSMENT ZONES

Survey segment	Number of active survey days	Estimated distances per day (km)	Estimated total line distance	Calculated level B harassment zone per day (km^2)
Lease Area	29	177.8	5,156	71.2
Cable Route Corridor	8	177.8	1,422	71.2

The parameters in Table 7 were used to estimate the potential take by incidental harassment for each segment of the HRG survey. Density data from Roberts *et al.* (2016b; 2017; 2018) were mapped within the boundary of the survey area for each segment (Figure 1 in application) using geographic information systems. For both survey segments, species densities, as reported by Roberts *et al.* (2016) within the maximum survey area, were averaged by season (spring and summer) based on the proposed HRG survey schedule (commencing no earlier than June 1, 2019). Potential take calculations were then based on the maximum average seasonal species density (between spring and summer) within the maximum survey area, given the survey start date and duration. Results of the take calculations by survey segment are provided in Table 8.

TABLE 8—MARINE MAMMAL DENSITY AND ESTIMATED TAKE BY LEVEL B HARASSMENT

Species	Lease area		Cable Corridor Route		Totals	
	Maximum average seasonal density [1] (No. /100 km [2])	Calculated Take (number)	Maximum average seasonal density [1] (No. /100 km [2])	Calculated Take (number)	Total take authorization (number)	Percent of population
North Atlantic right whale	0.051	1.063	0.051	0.288	[3] 0	
Humpback whale	0.466	9.631	0.102	0.581	10	1.11
Fin whale	0.328	6.773	0.128	0.729	[3] 0	
Sei whale	0.020	0.406	0.003	0.018	0	
Minke whale	0.757	15.643	0.171	0.9722	17	0.65
Pilot whale	0.100	2.073	0.034	0.195	[4 5] 10	<0.01
Harbor porpoise	1.252	25.874	0.690	3.931	30	<0.01
Bottlenose dolphin (WNA southern migratory coastal) [2]	0.000	0.000	49.102	104.944	105	2.8
Bottlenose dolphin (offshore) [2]	6.409	132.413	49.102	174.906	307	<0.01
Short beaked common dolphin	5.241	108.275	2.144	12.221	120	0.17
Atlantic white-sided dolphin	2.482	51.288	0.320	1.826	53	0.11
Atlantic spotted dolphin	8.895	183.772	3.493	19.910	204	0.46
Risso's dolphin	0.074	1.525	0.074	0.421	[4] 40	0.21

[1] Density values from Duke University (Roberts *et al.* 2016b; 2017; 2018).
[2] Estimates split based on bottlenose dolphin stock preferred water depths (Reeves *et al.* 2002; Waring *et al.* 2016).
[3] No take proposed for authorization, as discussed below.
[4] Adjusted for group size.
[5] For short-finned and long-finned pilot whales, percentage of stock taken is <0.01percent both species if all 10 takes are allocated separately to each species.

Since the calculated take value for pilot whales (2) is less than the mean group size (9.4), NMFS assumed that take of at least one group of pilot whales could occur (Silva et al, 2014). For bottlenose dolphin densities, Roberts *et al.* (2016b; 2017; 2018) does not differentiate by individual stock. Given the southern coastal migratory stock's propensity to be found in waters shallower than the 20 m depth isobath north of Cape Hatteras (Reeves *et al.* 2002; Waring *et al.* 2016), the Export Cable Corridor segment was roughly divided along the 20 m depth isobath. The Lease Area is located within depths exceeding 20 m, where the southern coastal migratory stock would be unlikely to occur. Roughly 40 percent of the Export Cable Corridor is 20 m or less in depth. Given the Export Cable Corridor area is estimated to take 8 days to complete survey activity, 3 days have been estimated for depths shallower than 20 m. Therefore, to account for the potential for mixed stocks within the Export Cable Corridor, 3 days has been applied to the take estimation equation for the southern coastal migratory stock and the remaining applied to the offshore stock (5 days). The offshore stock is the only stock of bottlenose dolphins that may occur in the lease area; therefore bottlenose dolphin densities within the Lease Area have been considered part of the offshore stock only for purposes of take estimation.

For Risso's dolphins, NMFS adjusted the calculated take number to account for group size. These dolphins are usually seen in groups of 12 to 40, but loose aggregations of 100 to 200 or more are seen occasionally (Reeves *et al.,* 2002). NMFS conservatively assumed that a group of 40 or several smaller groups not exceeding a total of 40 takes by Level B harassment.

The three ESA-listed large whales that could potentially be present in the survey area occur at very low densities, and the calculated numbers of potential acoustic exposures above the 160-dB threshold are small, *i.e.,* one right whale exposure, zero sei whale exposures, and eight fin whale exposures. In addition, Avangrid proposed a 500 m (1,640 ft) exclusion zone for the right whale and NMFS recommended a 200 m (656 ft) exclusion zone for sei and fin whales. Both of these measures are incorporated into the proposed IHA (see ''Proposed Mitigation''). These exclusion zones exceed (in the case of right whales) or equal (in the case of sei and fin whales) the distance to the conservatively calculated Level B harassment isopleth. Given the low likelihood of exposure in context of the proposed mitigation requirements (with relatively high detection probabilities for large whales at these distances during good visibility), we believe that there is not a reasonably anticipated potential for the specified activity to cause the disruption of behavioral patterns for these species. Therefore, we do not propose to authorize take by Level B harassment for these species.

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 such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such 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 such 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, 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.

Avangrid's application included a list of proposed mitigation measures during site characterization surveys utilizing HRG survey equipment. NMFS proposes the additional measure of establishing an exclusion zone of 200 m for sei and fin whales. The mitigation measures outlined in this section are based on protocols and procedures that have been successfully implemented and previously approved by NMFS (DONG Energy, 2016, ESS, 2013; Dominion, 2013 and 2014).

Visual Monitoring

Visual monitoring of designated exclusion and Level B harassment zones will ensure that (1) Any take of ESA-listed species would be limited; (2) exposure to underwater noise does not result in injury (Level A harassment), and (3) the number of instances of take does not exceed the authorized amounts. PSOs will coordinate to ensure 360° visual coverage around the vessel and conduct visual observations while free from distractions and in a consistent, systematic, and diligent manner. Visual PSOs shall immediately communicate all observations of marine mammals to the on-duty acoustic PSO(s), including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination. Any observations of marine mammal species by crew members aboard any vessel associated with the survey shall be relayed to the PSO team.

PSOs will establish and monitor applicable exclusion zones. During use of HRG acoustic sources (*i.e.,* anytime the acoustic source is active), occurrences of marine mammal species approaching the relevant exclusion zone will be communicated to the operator to prepare for the potential shutdown of the acoustic source. Exclusion zones are defined, depending on the species and context, below:

- 500 m (1,640 ft) exclusion zone for North Atlantic right whales;
- 200 m (656 ft) exclusion zone for sei and fin whales; and
- 100 m (328 ft) exclusion zone for other large cetaceans (*i.e.,* humpback whale, minke whale, pilot whale, Risso's dolphin).

The Level B harassment zone represents the zone within which marine mammals would be considered taken by Level B harassment and will encompass a distance of 200 m (656 ft) from survey equipment for all marine mammal species.

Pre-Clearance

Avangrid will implement a 30-minute clearance period of the exclusion zones. This will help ensure marine mammals are not in the exclusion zones prior to startup of HRG equipment. During this period the exclusion zones will be monitored by the PSOs, using the appropriate visual technology for a 30-minute period. The intent of pre-clearance observation is to ensure no marine mammal species are observed within the exclusion zones prior to the beginning of operation of HRG equipment. A PSO conducting pre-clearance observations must be notified immediately prior to initiating start of HRG equipment and the operator must receive confirmation from the PSO to proceed.

Activation of HRG equipment may not be initiated if any marine mammal is observed within the applicable exclusion zones as described above. If a marine mammal is observed within the applicable exclusion zone during the 30 minute pre-clearance period, activation of HRG equipment may not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (15 minutes for small delphinoid cetaceans and 30 minutes for all other species). Activation of HRG equipment may occur at times of poor visibility, including nighttime, if continuous visual observation and has occurred with no detections of marine mammals in the 30 minutes prior to beginning of start-up.

Shutdown Procedures

An immediate shutdown of the HRG survey equipment will be required if a marine mammal is sighted at or within its respective exclusion zone to minimize or avoid behavioral impacts to ESA-listed species. The vessel operator must comply immediately with any call for shutdown by the lead PSO. The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation.

Should there be any 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 or one of the species with a larger exclusion zone), visual PSOs may use best professional judgment in making the decision to call for a shutdown. 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 200 m Level B harassment zone, shutdown must occur.

Subsequent restart of the survey equipment can be initiated if the animal has been observed exiting its respective exclusion zone within 30 minutes of the shutdown or an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and 30 minutes for all other species).

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 pre-clearance protocols, if PSOs have maintained constant observation and no detections of any marine mammal have occurred within the respective exclusion zones.

Vessel Strike Avoidance

In order to avoid striking animals, vessel operators and crews must maintain a vigilant watch for all marine mammal species and slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size. A visual observer aboard the vessel must monitor a vessel strike avoidance zone 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 distinguish marine mammal species from other phenomena and 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. Vessel strike avoidance measures will include the following:

• All vessels (*e.g.,* source vessels, chase vessels, supply 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: Any Dynamic Management Areas (DMA) when in effect, and the Mid-Atlantic Seasonal Management Areas (SMA) (from November 1 through April 30). See 50 CFR 224.105 and *www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-ship-strikes-north-atlantic-right-whales* for specific detail regarding these areas.

• Vessel speeds must also be reduced to 10 knots or less, regardless of location, 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. If a whale is observed but cannot be confirmed as a species other than a right 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 all other baleen whales and sperm 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.

• These requirements do not apply in any 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.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means 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.

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 and Reporting Measures

Visual Monitoring

Visual monitoring shall be conducted by NMFS-approved PSOs. PSO resumes shall be provided to NMFS for approval prior to commencement of the survey. Avangrid must use independent, dedicated, trained PSOs, meaning that the PSOs must be employed by a third-party observer provider, must 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).

Observations shall take place from the highest available vantage point on the survey vessel. General 360-degree scanning shall occur during the monitoring periods, and target scanning by the PSO shall occur when alerted of a marine mammal presence. An observer team comprising a minimum of four NMFS-approved PSOs, operating in shifts, will be stationed aboard the survey vessel. PSO's will work in shifts such that no one monitor will work more than 4 consecutive hours without a 2-hour break or longer than 12 hours during any 24-hour period. During daylight hours the PSOs will rotate in shifts of 1 on and 3 off, and during nighttime operations PSOs will work in pairs.

PSOs must have all equipment (including backup equipment) needed to adequately perform necessary tasks, including accurate determination of distance and bearing to observed marine mammals. PSOs will be equipped with binoculars and have the ability to estimate distances to marine mammals located in proximity to their established zones using range finders. Reticulated binoculars will also be available to PSOs for use as appropriate based on conditions and visibility to support the siting and monitoring of marine species. Cameras of appropriate quality will be used for photographs and video to record sightings and verify species identification. Each PSO must have a camera and backup cameras should be available. During night operations, night-vision equipment (night-vision goggles with thermal clip-ons) and infrared technology will be used. Position data will be recorded using hand-held or vessel global positioning system (GPS) units for each sighting. Radios for each PSO are required in order to communicate among vessel crew and PSOs. PSO must also have compasses and any other tools necessary to perform other PSO tasks.

PSOs shall be responsible for visually monitoring and identifying marine mammals approaching or entering the established monitoring zones as well as beyond the monitoring zones to the maximum extent possible. PSOs will record animals both within and beyond the monitoring zones during survey activities.

Data on all PSO observations must be recorded based on standard PSO collection requirements. PSOs must use standardized data forms, whether hard copy or electronic. This shall include the following:

- Vessel names (source vessel and other vessels associated with survey), vessel size and type, maximum speed capability of vessel, port of origin, and call signs;
- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Date and participants of PSO briefings;
- 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);
- Survey activity information, such as acoustic source power output while in operation, and any other notes of significance (*i.e.,* pre-ramp-up survey, ramp-up, shutdown, testing, ramp-up completion, end of operations, etc.);
- If a marine mammal is sighted, the following information should be reported:

(a) Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);

(b) PSO who sighted the animal;

(c) Time of sighting;

(d) Vessel location at time of sighting;

(e) Water depth;

(f) Direction of vessel's travel (compass direction);

(g) Direction of animal's travel relative to the vessel;

(h) Pace of the animal;

(i) Estimated distance to the animal and its heading relative to vessel at initial sighting;

(j) 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;

(k) Estimated number of animals (high/low/best);

(l) Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);

(m) 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);

(n) 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);

(o) Animal's closest point of approach and/or closest distance from the center point of the acoustic source;

(p) Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, data acquisition, other); and

(q) 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.

Proposed Reporting Measures

Within 90 days after completion of survey activities, a final report will be provided to NMFS that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, estimates the number of marine mammals estimated to have been taken during survey activities, and provides an interpretation of the results and effectiveness of all mitigation and monitoring. All raw observational data shall be made available to NMFS. The draft report must be accompanied by a certification from the lead PSO as to the accuracy of the report, and the lead PSO may submit directly to NMFS a statement concerning implementation and effectiveness of the required mitigation and monitoring. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS. A final report must be submitted within 30 days following resolution of any comments on the draft report.

Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified HRG activities lead to an injury of a marine mammal (Level A harassment) or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), Avangrid would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the NMFS Southeast Regional Stranding Coordinator. The report would include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and 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 event. NMFS would work with Avangrid to minimize reoccurrence of such an event in the future. Avangrid would not resume activities until notified by NMFS.

In the event that Avangrid discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition), Avangrid would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the NMFS Southeast 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 Avangrid to determine if modifications in the activities are appropriate.

In the event that Avangrid discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Avangrid would report the incident to the Chief of the Permits and Conservation Division, Office of

Protected Resources, and the NMFS Southeast Regional Stranding Coordinator, within 24 hours of the discovery. Avangrid would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS. Avangrid may continue its operations under such a case.

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. 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'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, this introductory discussion of our analyses applies to all the species listed in Table 8, 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.

As discussed in the ''Potential Effects of the Specified Activity on Marine Mammals and Their Habitat'' section, PTS, masking, non-auditory physical effects, and vessel strike are not expected to occur. Marine mammal habitat may be impacted by elevated sound levels but these impacts would be short term. Feeding behavior is not likely to be significantly impacted. 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 availability of similar habitat and resources in the surrounding area, and the lack of important or unique marine mammal habitat, 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. Additionally, there are no feeding areas or mating grounds known to be biologically important to marine mammals within the proposed project area with the exception of a migratory BIA for North Atlantic right whales described below.

Biologically Important Areas (BIA)

The proposed survey area includes a biologically important migratory area for North Atlantic right whales (effective March-April and November-December) that extends from Massachusetts to Florida (LaBrecque, *et al.,* 2015). As previously noted, no take of North Atlantic right whales has been proposed, and HRG survey operations will be required to shut down at 500 m to further minimize any potential effects to this species. The fact that the spatial acoustic footprint of the proposed survey is very small relative to the spatial extent of the available migratory habitat leads us to expect that right whale migration will not be impacted by the proposed survey.

Unusual Mortality Events (UME)

A UME is defined under the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response. Two UMEs are ongoing and under investigation relevant to the HRG survey area for species for which authorization of take is proposed. These involve humpback whales and minke whales. There is currently no direct connection between the UMEs, as there is no evident cause of stranding or death that is common across the species involved in the UMEs. Additionally, strandings across the two species are not clustering in space or time. We are proposing to take only limited numbers of humpback (10) and minke whale (17) by Level B harassment in the form of minor, short-term behavioral modifications that are unlikely to directly or indirectly result in strandings or mortality.

Based on the foregoing preliminary information, direct physical interactions (ship strikes and entanglements) appear to be responsible for many of the UME mortalities recorded. The HRG survey with the proposed mitigation and monitoring is not likely to result in any mortalities. Fishing gear and in-water lines will not be employed by the survey vessel, and ship speed and avoidance mitigation measures will minimize risk of ship strikes.

The proposed mitigation measures are expected to reduce the number and/or severity of takes by preventing animals from being exposed to sound levels that have the potential to cause Level B harassment during HRG survey activities. Vessel strike avoidance requirements will further mitigate potential impacts to marine mammals during vessel transit to and within the survey area.

Avangrid did not request, and NMFS is not proposing to authorize, take of marine mammals by serious injury or mortality. NMFS expects that most takes would primarily consist of short-term Level B behavioral harassment in the form of temporary vacating of the area or decreased foraging (if such activity were occurring). These reactions are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007). Since the source is mobile, a specified area would be ensonified by sound levels that could result in take for only a short period. Additionally, required mitigation measures would reduce exposure to sound that could result in harassment.

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 injury is anticipated or authorized;
- Feeding behavior is not likely to be significantly impacted as effects on species that serve as prey species for marine mammals from the proposed 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 biologically important for migration of the North Atlantic right whale, migration would not be affected since project activities would occur in such a comparatively small area. In addition, mitigation measures will be required to shut down sound sources at 500 m to further minimize any potential for effects to this species; and

• The proposed mitigation measures, including visual monitoring and shutdowns, are expected to minimize potential impacts to marine mammals, particularly in light of the small size of the take zones.

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 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. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities relative to the species.

The numbers of marine mammals that we propose for authorization to be taken, for all species and stocks, would be considered small relative to the relevant stocks or populations (less than 3 percent for the bottlenose dolphin Western North Atlantic, southern migratory coastal stock and less than one percent for all other species and stocks proposed for authorization). See Table 8. 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 sizes of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of marine mammals 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 (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.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Avangrid for HRG survey activities during geophysical survey activities off the Coast of Virginia and North Carolina from June 1, 2019, through May 31, 2020, 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/permit/incidental-take-authorizations-under-marine-mammal-protection-act*.

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 HRG survey. We also request comment on the potential for 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 our final decision on the request for MMPA authorization.

On a case-by-case basis, NMFS may issue a one-year IHA renewal with an expedited public comment period (15 days) when (1) another year of identical or nearly identical activities as described in the Specified Activities section is planned or (2) the activities would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section, provided all of the following conditions are met:

• A request for renewal is received no later than 60 days prior to expiration of the current IHA.

• The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the proposed Renewal 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 because only a subset of the initially analyzed activities remain to be completed under the Renewal); and

(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: April 22, 2019.

Catherine Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–08361 Filed 4–24–19; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Academic Research Council Meeting

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Academic Research Council (ARC or Council) of the Bureau of Consumer Financial Protection (Bureau). The notice also describes the functions of the Council.

DATES: The meeting date is Friday, May 10, 2019, 10:30 a.m.–12:00 p.m. eastern standard time.

ADDRESSES: The meeting is being held via conference call. RSVP is requested to receive the conference dial-in.

FOR FURTHER INFORMATION CONTACT: Kim George, Outreach and Engagement Associate, at 202–435–7884, or *CFPB_CABandCouncilsEvents@cfpb.gov*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the of the ARC Charter provides that the pursuant to the executive and administrative powers conferred on the Bureau by section 1012 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director established the Academic Research Council under agency authority. Section 3 of the ARC Charter states:

The committee will (1) provide the Bureau with advice about its strategic research planning process and research agenda, including views on the research that the Bureau should conduct relating to consumer financial products or services, consumer behavior, cost-benefit analysis, or other topics to enable the agency to further its statutory purposes and objectives; and (2) provide the Office of Research with technical advice and feedback on research methodologies, data collection strategies, and methods of analysis, including methodologies and strategies for quantifying the costs and benefits of regulatory actions.

II. Agenda

The Academic Research Council will discuss methodology and direction for consumer finance research at the Bureau.

Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. The Bureau will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the ARC members for consideration. Individuals who wish to join the Academic Research Council must RSVP via this link *https://consumer-financial-protection-bureau.forms.fm/may-2019-cfpb-academic-research-council-arc-meeting* by noon, May 9, 2018. Members of the public must RSVP by the due date.

III. Availability

The Council's agenda will be made available to the public on April 25, 2019 via *consumerfinance.gov*. Individuals should express in their RSVP if they require a paper copy of the agenda.

A recording and transcript of this meeting will be available after the meeting on the Bureau's website *consumerfinance.gov*.

Dated: April 16, 2019.

Kirsten Sutton,

Chief of Staff, Consumer Financial Protection Bureau.

[FR Doc. 2019–08129 Filed 4–24–19; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Inland Waterways Users Board Meeting Notice

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the U.S. Army Corps of Engineers, Inland Waterways Users Board (Board). This meeting is open to the public. For additional information about the Board, please visit the committee's website at *http://www.iwr.usace.army.mil/Missions/Navigation/InlandWaterwaysUsersBoard.aspx*.

DATES: The Army Corps of Engineers, Inland Waterways Users Board will meet from 8:00 a.m. to 12:00 p.m. on May 23, 2019. Public registration will begin at 7:15 a.m.

ADDRESSES: The Inland Waterways Users Board meeting will be conducted at The Westin New Orleans Canal Place, 100 Rue Iberville, New Orleans, Louisiana 70130, 504–566–7006.

FOR FURTHER INFORMATION CONTACT: Mr. Mark R. Pointon, the Designated Federal Officer (DFO) for the committee, in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR–GM, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–6438; and by email at *Mark.Pointon@usace.army.mil*. Alternatively, contact Mr. Kenneth E. Lichtman, the Alternate Designated Federal Officer (ADFO), in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR–GW, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–8083; and by email at *Kenneth.E.Lichtman@usace.army.mil*.

SUPPLEMENTARY INFORMATION: The committee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The Board is chartered to provide independent advice and recommendations to the Secretary of the Army on construction and rehabilitation project investments on the commercial navigation features of the inland waterways system of the United States. At this meeting, the Board will receive briefings and presentations regarding the investments, projects and status of the inland waterways system of the United States and conduct discussions and deliberations on those matters. The Board is interested in written and verbal comments from the public relevant to these purposes.

Agenda: At this meeting the agenda will include the status of funding for inland and coastal Navigation; status of the Inland Waterways Trust Fund (IWTF) and project updates; status of the construction activities for Olmsted Locks and Dam Project, the Locks and Dams 2, 3, and 4 on the Monongahela River Project, the Chickamauga Lock Project and the Kentucky Lock Project; an update of the Upper Ohio River Navigation Study; an update of the Mississippi River and Illinois Waterway Navigation and Environmental Sustainability Project (NESP); an update of the Calcasieu Lock study and results of simulations; and discussion of innovative design techniques and standardization of features for inland waterway projects.

Availability of Materials for the Meeting. A copy of the agenda or any updates to the agenda for the May 23, 2019 meeting. The final version will be provided at the meeting. All materials will be posted to the website after the meeting.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.1

65, and subject to the availability of space, this meeting is open to the public. Registration of members of the public who wish to attend the meeting will begin at 7:15 a.m. on the day of the meeting. Seating is limited and is on a first-to-arrive basis. Attendees will be asked to provide their name, title, affiliation, and contact information to include email address and daytime telephone number at registration. Any interested person may attend the meeting, file written comments or statements with the committee, or make verbal comments from the floor during the public meeting, at the times, and in the manner, permitted by the committee, as set forth below.

Special Accommodations: The meeting venue is fully handicap accessible, with wheelchair access. Individuals requiring special accommodations to access the public meeting or seeking additional information about public access procedures, should contact Mr. Pointon, the committee DFO, or Mr. Lichtman, the ADFO, at the email addresses or telephone numbers listed in the **FOR FURTHER INFORMATION CONTACT** section, at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the Board about its mission and/or the topics to be addressed in this public meeting. Written comments or statements should be submitted to Mr. Pointon, the committee DFO, or Mr. Lichtman, the committee ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section in the following formats: Adobe Acrobat or Microsoft Word. The comment or statement must include the author's name, title, affiliation, address, and daytime telephone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the committee DFO or ADFO at least five (5) business days prior to the meeting so that they may be made available to the Board for its consideration prior to the meeting. Written comments or statements received after this date may not be provided to the Board until its next meeting. Please note that because the Board operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection.

Verbal Comments: Members of the public will be permitted to make verbal comments during the Board meeting only at the time and in the manner allowed herein. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least three business (3) days in advance to the committee DFO or ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section. The committee DFO and ADFO will log each request to make a comment, in the order received, and determine whether the subject matter of each comment is relevant to the Board's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three (3) minutes during this period, and will be invited to speak in the order in which their requests were received by the DFO and ADFO.

Mark R. Pointon,

Designated Federal Officer and Executive Secretary, Inland Waterways Users Board.

[FR Doc. 2019–08265 Filed 4–24–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0035]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Part D Discretionary Grant Application—Individuals With Disabilities Education Act (1890–0001)

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before May 28, 2019.

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–2019–ICCD–0035. 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 Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Darcalyn Darling, 202–245–7542.

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: Part D Discretionary Grant Application—Individuals with Disabilities Education Act (1890–0001).

OMB Control Number: 1820–0028.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 800.

Total Estimated Number of Annual Burden Hours: 21,200.

Abstract: Under the Individuals with Disabilities Education Act discretionary grants are authorized to support technology, State personnel development, personnel preparation, parent training and information, and technical assistance activities. This grant application provides the forms and information necessary for applicants to submit an application for funding, and information for use by technical reviewers to determine the quality of the application.

Dated: April 22, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–08346 Filed 4–24–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: EIA requests a three-year extension, with changes to the Electric Power & Renewable Electricity Surveys (EPRES) as required under The Paperwork Reduction Act of 1995. The EPRES consists of nine surveys, including annual, monthly and a daily survey. These surveys collect data from entities involved in the production, transmission, delivery, and sale of electricity, and in maintaining the reliable operation of the power system. The data collected are the primary source of information on the nation's electric power system. The renewable energy survey collects information on the manufacture, shipment, import, and export of photovoltaic cells and modules, and is the primary national source of information on these topics.

DATES: EIA must receive all comments on this proposed information collection no later than June 24, 2019. If you anticipate any difficulties in submitting your comments by the deadline, contact the person listed in the **ADDRESSES** section of this notice as soon as possible.

ADDRESSES: Send your comments to Sara Hoff, Office of Electricity, Renewables, and Uranium Statistics, U.S. Energy Information Administration, Forrestal Building, U.S. Department of Energy, 1000 Independence Ave. SW, EI–23, Washington, DC 20585. Submission via email to *Electricity2020@eia.gov* is recommended.

FOR FURTHER INFORMATION CONTACT: Sara Hoff, (202) 586–1242 email: *Electricity2020@eia.gov*. The forms and instructions are available on EIA's website at *https://www.eia.gov/survey/*.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.* 1905–0129.

(2) *Information Collection Request Title:* Electric Power & Renewable Electricity Surveys;

(3) *Type of Request:* Renewal with changes;

(4) *Purpose:* EIA's EPRES consists of the following nine surveys:

Form EIA–63B, *Photovoltaic Module Shipments Report;*

Form EIA–411, *Coordinated Bulk Power Supply Program Report;*

Form EIA–860, *Annual Electric Generator Report;*

Form EIA–860M, *Monthly Update to the Annual Electric Generator Report;*

Form EIA–861, *Annual Electric Power Industry Report;*

Form EIA–861S, *Annual Electric Power Industry Report (Short Form);*

Form EIA–861M, *Monthly Electric Power Industry Report;*

Form EIA–923, *Power Plant Operations Report;*

Form EIA–930, *Balancing Authority Operations Report.*

Form EIA–63B *Photovoltaic Module Shipments Report* tracks photovoltaic module manufacturing, shipments, technology types, revenue, and related information. The data collected on this form are used by DOE, Congress, other government and non-government entities, and the public to monitor the current status and trends of the photovoltaic industry and to evaluate the future of the industry.

Form EIA–411 *Coordinated Bulk Power Supply Program Report* collected information relating to the reliability of the electric power system in the lower 48 states, including regional electricity supply and demand projections for a 10-year advance period, the characteristics, and frequency of outages occurring on the Bulk Electric System, and other information on the transmission system and supporting facilities. The data are collected from the regional reliability entities by the North American Electric Reliability Corp., (NERC), which then organizes and edits the information and submits the data to EIA.

Form EIA–860, *Annual Electric Generator Report* collects data on existing and planned electric generation plants, and associated equipment including generators, boilers, cooling systems, and environmental control systems. Data are collected from all existing units and from planned units scheduled for initial commercial operation within ten years of the specified reporting period (depending on the type of power plant).

Form EIA–860M, *Monthly Update to the Annual Electric Generator Report* collects data on the status of proposed new generators scheduled to begin commercial operation within the future 12-month period; and existing generators that have proposed modifications that are scheduled for completion within one month. The information is needed to ensure a complete and accurate inventory of the nation's generating fleet, for such purposes as reliability and environmental analysis.

Form EIA–861, *Annual Electric Power Industry Report* collects annual information on the retail sale, distribution, transmission, and generation of electric energy in the United States and its territories. The data include related activities such as energy efficiency and demand response programs. In combination with Form EIA–861S short form and the monthly Form EIA–861M, this annual survey provides coverage of sales to ultimate customers of electric power and related activities. Form EIA–861S, *Annual Electric Power Industry Report (Short Form)* collects a limited set of information annually from small companies involved in the retail sale of electricity. A complete set of annual data are collected from large companies on Form EIA–861. The small utilities that currently report on Form EIA–861S are required to complete Form EIA–861 once every eight years to provide updated information for the statistical estimation of uncollected data. Form EIA–861M, *Monthly Electric Power Industry Report* collects monthly information from a sample of electric utilities, energy service providers and distribution companies that sell or deliver electric power to end users. Data included on this form includes sales

and revenue for end-use sectors—residential, commercial, industrial, and transportation. This survey is the monthly complement to the annual data collection from the universe of respondents that report on Form EIA–861 and Form EIA–861S.

Form EIA–923, *Power Plant Operations Report* collects information from electric power plants in the United States on electric power generation, energy source consumption, end of reporting period fossil fuel stocks, as well as the quality and cost of fossil fuel receipts.

Form EIA–930, *Balancing Authority Operations Report* collects a comprehensive set of the current day's system demand data on an hourly basis and the prior day's basic hourly electric system operating data on a daily basis. The data provide a basic measure of the current status of electric systems in the United States and can be used to compare actual system demand with the day-ahead forecast thereby providing a measure of the accuracy of the forecasting used to commit resources. In addition, the data can be used to address smart grid related issues such as integrating wind and solar generation, improving the coordination of natural gas and electric short-term operations and expanding the use of demand response, storage, and electric vehicles in electric systems operations.

(4a) *Proposed Changes to Information Collection:*

Form EIA–411

EIA proposes to discontinue the use of Form EIA–411. Data reported on Form EIA–411 are collected by NERC and sent to EIA. NERC annually publishes an Electricity Supply and Demand (ES&D) public-use database at *https://www.nerc.com/pa/RAPA/ESD/Pages/default.aspx.* This ES&D database includes all the data that EIA published from the information reported on Form EIA–411. The ES&D public database contains more detail than the data EIA published.

(5) *Annual Estimated Number of Respondents:* 19,803:
Form EIA–63B has 55 respondents;
Form EIA–860 has 4,757 respondents;
Form EIA–860M has 312 respondents;
Form EIA–861 has 2,262 respondents;
Form EIA–861S has 1,157 respondents;
Form EIA–861M has 620 respondents;
Form EIA–923 has 10,575 respondents;
Form EIA–930 has 65 respondents.

(6) *Annual Estimated Number of Total Responses:* 75,220.

(7) *Annual Estimated Number of Burden Hours:* 169,870 hours.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $12,573,777 (169,870 burden hours times $74.02 per hour). EIA estimates that there are no additional costs to respondents associated with the surveys other than the costs associated with the burden hours since the information is maintained during normal course of business.

Comments are invited on whether or not: (a) The proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have a practical utility; (b) EIA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) EIA can improve the quality, utility, and clarity of the information it will collect; and (d) EIA can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

Statutory Authority: 15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*

Signed in Washington, DC, on April 19, 2019.

Nanda Srinivasan,

Director, Office of Survey Development and Statistical Integration U. S. Energy Information Administration.

[FR Doc. 2019–08319 Filed 4–24–19; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1219]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 24, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.ongele@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1219.

Title: Connect America Fund-Alternative Connect America Cost Model Support.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 1,100 unique respondents; 1,100 responses.

Estimated Time per Response: 0.5 hours–2 hours.

Frequency of Response: On occasion and one-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 700 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: We note that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific

form unless directed to do so by the Commission.

Needs and Uses: The Commission is requesting approval for this revised collection. In March 2016, the Commission adopted significant reforms to place the universal service support program on solid footing for the next decade to preserve and advance voice and broadband service in areas served by rate-of-return carriers. Connect America Fund; ETC Annual Reports and Certifications; Establishing Just and Reasonable Rates for Local Exchange Carriers; Developing a Unified Intercarrier Compensation Regime, WC Docket Nos. 10–90, 14–58, 07–135, 05–337, 03–109; CC Docket Nos. 01–92, Report and Order, Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking, FCC 16–33 (*2016 Rate-of-Return Reform Order*).

The Commission adopted a voluntary path for rate-of-return carriers to receive model-based support in exchange for making a commitment to deploy broadband-capable networks meeting certain service obligations to a pre-determined number of eligible locations in a state. By creating a voluntary pathway to model-based support, the Commission will spur new broadband deployment in rural areas. In several subsequent orders and public notices, the Commission has further refined this voluntary pathway, and in the December 2018 Rate-of-Return Reform Order, the Commission adopted a second pathway for carriers that did not elect the first pathway. Connect America Fund; ETC Annual Reports and Certifications; Establishing Just and Reasonable Rates for Local Exchange Carriers; Developing a Unified Intercarrier Compensation Regime, WC Docket Nos. 10–90, 14–58, 07–135, 05–337, 03–109; CC Docket Nos. 01–92, Report and Order, Further Notice of Proposed Rulemaking, and Order on Reconsideration, FCC 18–176 (*December 2018 Rate-of-Return Reform Order*). Additionally, in the *2016 Rate-of-Return Reform Order,* the Commission also adopted reforms to the universal service mechanisms used to determine support for rate-of-return carriers not electing model-based support. Among other such reforms, the Commission adopted an operating expense limitation to improve carriers' incentives to be prudent and efficient in their expenditures, a capital investment allowance to better target support to those areas with less broadband deployment, and broadband deployment obligations to promote ''accountability from companies receiving support to ensure that public investment are used wisely to deliver intended results.'' In the *December 2018 Rate-of-Return Order,* the Commission further modified or, in the case of the capital investment allowance, eliminated these requirements. This information collection addresses the revised burdens associated with those reforms.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–08311 Filed 4–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation—Cap Adjustment

AGENCY: Federal Maritime Commission.

ACTION: Notice.

DATES: The Adjusted Cap amount will be effective June 24, 2019.

FOR FURTHER INFORMATION CONTACT: Sandra L. Kusumoto, Director, Bureau of Certification and Licensing, 202–523–5787, *skusumoto@fmc.gov*.

SUPPLEMENTARY INFORMATION: In accordance with the Final Rule published in the **Federal Register** (FR) of February 27, 2013 (78 FR 13268), the Director, Bureau of Certification and Licensing is required to calculate the Adjusted Cap amount for financial responsibility for indemnification of passengers for nonperformance of transportation and transmit that information to the Commission's Office of the Secretary for publication on the Commission's website and in the **Federal Register**. The cap automatically adjusts every two years after the date the cap reached $30 million (April 2, 2015), based on changes in the U.S. Bureau of Labor Statistics' (BLS) Consumer Price Index for all Urban Consumers (CPI–U), and is rounded to the nearest $1 million.

The formula used to determine the percent change is as follows:

$$\text{Percent Change in the Annual CPI-U} = \frac{(\text{Annual CPI-U for 2018} - \text{Annual CPI-U for 2015})}{\text{Annual CPI-U for 2015}} \times 100$$

Based on the percent change calculated, the Escalation Formula for the cap adjustment is calculated. The formula uses a Base Cap of $30 million set from April 2, 2015, as the cap upon which all subsequent cap adjustment calculations will be determined. The calculation for the Adjusted Cap is then rounded to the nearest $1 million. The following is the Escalation Formula used to determine the Adjusted Cap:

$$\text{Adjusted Cap} = \frac{(\text{Base Cap} \times \text{Change in the Annual CPI - U})}{100} + \text{Base Cap}$$

The index percent change for use in 2019 was calculated to be 5.945 and the Adjusted Cap was calculated to be $31.8 million. The Adjusted Cap rounded to the nearest $1 million is $32 million. The current cap of $30 million remains in effect until the Adjusted Cap of $32 million becomes effective. Thereafter and until the next adjustment, the cap for financial responsibility for indemnification of passengers for nonperformance of transportation shall increase to $32 million. The next adjustment will be conducted in 2021.

Rachel Dickon,

Secretary.

[FR Doc. 2019–08374 Filed 4–24–19; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission,

Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 201295.

Agreement Name: Australia New Zealand South Pacific Islands Agreement.

Parties: PDL International Pte Ltd.; ANL Singapore Pte Ltd. d/b/a Sofrana ANL Pte Ltd.; Pacific Form Line (Group) Limited, and Neptune Pacific Line, Inc.

Filing Party: David Monroe; GKG Law, P.C.

Synopsis: The agreement authorizes the parties to share vessels in the trade between Australia, New Zealand, New Caledonia, Vanuatu, Fiji, Tonga, and Samoa on the one hand, and American Samoa on the other hand. The Agreement would also authorize the parties to cooperate in a revenue pooling arrangement in the trade.

Proposed Effective Date: 5/27/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/21386.

Dated: April 19, 2019.

Rachel Dickon,

Secretary.

[FR Doc. 2019–08372 Filed 4–24–19; 8:45 am]

BILLING CODE 6731–AA–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 notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 10, 2019.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *William Richard Vanover, Jr., Alice, Texas;* to acquire voting shares of San Diego Bancshares, Inc. and, thereby indirectly acquire shares of First State Bank of San Diego, both of San Diego, Texas.

Board of Governors of the Federal Reserve System, April 22, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–08359 Filed 4–24–19; 8:45 am]

BILLING CODE 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 applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 23, 2019.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Ford Management III, L.P., Ford Financial Fund III, L.P. and EB Acquisition Company II LLC, all of Dallas, Texas;* each to become a bank holding company by acquiring shares of Mechanics Bank, Walnut Creek, California.

Board of Governors of the Federal Reserve System, April 22, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–08360 Filed 4–24–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–19–003, Evaluation of Return to School Programs for Traumatic Brain Injury (TBI).

Date: June 18–19, 2019.

Time: 8:30 a.m.–5:30 p.m., EDT.

Place: Hilton Garden Inn Atlanta—Buckhead, 3342 Peachtree Road NE, Atlanta, GA 30326.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Kimberly Leeks, Ph.D., M.P.H., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (770) 488–6562, *KLeeks@cdc.gov*.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–08339 Filed 4–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–19–002, Research Grants to Identify Effective Strategies for Opioid Overdose Prevention.

Date: June 25–26, 2019.

*Time: 8:*30 a.m.–5:30 p.m., EDT.

Place: Hilton Garden Inn Atlanta—Buckhead, 3342 Peachtree Road NE, Atlanta, GA 30326

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel Walters, Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (404) 639–0913, *MWalters@cdc.gov*.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–08338 Filed 4–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict.

Date: June 27, 2019.

Time: 1:00 p.m.–4:00 p.m. EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Nina Turner, Ph.D., Scientific Reviewer Officer, Office of Extramural Programs, 1095 Willowdale Road, Morgantown, WV 26506, (304) 285–5976, *nxt2@cdc.gov*.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–08337 Filed 4–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Evaluation of the Sexual Risk Avoidance Education (SRAE) Program.

OMB No.: [NEW].

Description: The Administration for Children and Families (ACF) proposes a data collection effort related to the National Evaluation of the Sexual Risk Avoidance Education (SRAE) Program—National Descriptive Study.

The National Descriptive Study (of the National Evaluation of the SRAE Program) has multiple components. This information collection request only pertains to the Early Implementation Study, which will provide an early catalogue of SRAE programs' implementation. ACF seeks approval to collect the following information:

—*Survey for Use with SRAE grantees.* The purpose of this collection effort is to conduct surveys with administrators/program directors in each of the states/organizations that received SRAE grants to better understand what key decisions states/organizations made regarding the design of their SRAE-funded programs and why they made those decisions.

—*Interview Guide for Use with SRAE grantees.* The purpose of this collection effort is to conduct semi-structured interviews, that follow-on the surveys, with administrators/program directors in each of the states/organizations that received SRAE grants: the interviews will offer long-answer, qualitative responses to key questions, to better understand what key decisions states/organizations made regarding the design of their SRAE-funded programs and why they made those decisions.

Respondents: State level administrators; Agency administrators; Organization heads; Project directors.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Survey for SRAE Grantees	85	28	1	1.5	42
Interview Guide for SRAE Grantees	85	28	1	1.5	42

Estimated Total Annual Burden Hours: 84 hours.

Additional Information: Copies of the proposed collection may be obtained by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08322 Filed 4–24–19; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0762]

Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles; Guidance for Government Public Health and Emergency Response Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for government public health and emergency response stakeholders entitled ''Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.'' This document provides guidance to government stakeholders on testing to extend the expiration date—under the Federal Food, Drug, and Cosmetic Act (FD&C Act)—of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency. This guidance has been prepared in response to requests from States asking FDA what would be necessary to provide confidence that stockpiled doxycycline tablets and capsules have retained their original quality beyond the manufacturer's labeled expiration date so the replacement of stockpiled product could be deferred. This guidance and any resulting expiration date extensions authorized by FDA do not apply to doxycycline available commercially or otherwise held for any other nonemergency purpose. This guidance finalizes the draft guidance issued in April 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on April 25, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0762 for ''Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division

of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Frederick Ensor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6652, Silver Spring, MD 20993–0002, 240–402–2733.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for government public health and emergency response stakeholders entitled ''Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.'' A number of government public health and emergency response stakeholders maintain stockpiles of doxycycline tablets or capsules for post-exposure prophylaxis (PEP) or treatment of inhalational anthrax in the event of an anthrax emergency. States have asked FDA what would be necessary to provide confidence that stockpiled doxycycline tablets and capsules have retained their original quality (*i.e.,* purity and potency) beyond the manufacturer's labeled expiration date so the replacement of stockpiled product could be deferred. This document provides guidance to government stakeholders on testing to extend the expiration date—under section 564A(b) of the FD&C Act (21 U.S.C. 360bbb–3a(b))—of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency.

This guidance applies to both doxycycline monohydrate and doxycycline hyclate tablets and capsules equivalent to 50 milligrams (mg) and 100 mg of doxycycline that are indicated for PEP or treatment of inhalational anthrax. Where doxycycline is mentioned throughout this guidance, it is meant to include both the hyclate and monohydrate forms of the drug that are indicated for PEP or treatment of inhalational anthrax.

This guidance finalizes the draft guidance issued in April 2017. Those comments received on the draft guidance did not result in any policy changes but in some instances did result in clarifying language in the final guidance document.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0595.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: April 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08349 Filed 4–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0934]

Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics With Continuous Outcomes; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.'' The draft guidance, when finalized, will represent the current thinking of FDA on adjusting for covariates in randomized clinical trials for drugs and biologics, focusing on randomized clinical trials with continuous endpoints.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–0934 for ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov*

or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott N. Goldie, Center for Drug Evaluation and Research, Office of Biostatistics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.'' This guidance provides recommendations for the use of analysis of covariance (ANCOVA) in randomized clinical trials.

The target population for a new drug or biologic usually includes individuals with diverse prognostic factors, and the population studied in clinical trials should reflect this diversity. However, baseline differences in prognostic factors impair the detection and estimation of treatment effects. Incorporating prognostic factors in the statistical analysis of clinical trial data can mitigate this impairment and can result in a more efficient use of data to demonstrate and quantify the effects of treatment. The International Council for Harmonisation guidance for industry entitled ''E9 Statistical Principles for Clinical Trials'' briefly addresses these issues (*https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073137.pdf*). This guidance provides more detailed recommendations for the use of ANCOVA in randomized clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 312.23 for investigational new drug application content and format have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: April 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08353 Filed 4–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Development of Appropriate Pediatric Formulations and Pediatric Drug Delivery Systems.

Date: May 31, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Paek-Gyu Lee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, (301) 613–2064, *leepg@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Basic Neurodevelopmental Biology of Circuits and Behavior.

Date: June 3, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Emerging Imaging Technologies in Neuroscience Study Section.

Date: June 6–7, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.

Contact Person: Sharon S. Low, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7846, Bethesda, MD 20892, 301–237–1487, *lowss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroengineering and Cognition Special Emphasis Panel.

Date: June 7, 2019.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–875–2215, *qinmei@csr.nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community-Level Health Promotion Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428, *wup4@csr.nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Dr., Chicago, IL 60601.

Contact Person: Mary G. Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–915–6301, *marygs@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–NS–18–041: Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain.

Date: June 14, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cristina Backman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, 301–480–9069, *cbackman@mail.nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Bioengineering of Neuroscience, Vision and Low Vision Technologies Study Section.

Date: June 18–19, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Robert C. Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: June 19–20, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08313 Filed 4–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: May 31, 2019.

Time: 8:30 a.m. to 2:30 p.m.

Agenda: Discussion of Programs.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: W. Keith Hoots, MD, Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 9030, Bethesda, MD 20892, 301–435–0080, *hootswk@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 19, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–08312 Filed 4–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7014–N–12]

60-Day Notice of Proposed Information Collection: Pay for Success Pilot Application Requirements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of

information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* June 24, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Josh Geyer, Office of Environment and Energy, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Joshua.m.geyer@hud.gov* or telephone (415) 489–6418. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Pay for Success Pilot Application Requirements.

OMB Approval Number: 2502–0613.

OMB Expiration Date: 1/31/2020.

Type of Request: This is a revision of a currently approved collection.

****Form Numbers:* HUD–2530, SF 424 family of forms, HUD–2880, HUD–424–CBW, HUD–9250, Certification of Owner Eligibility, Cooperative Agreement, Site-Specific Environmental Review (Part 1 of 2), and Office of Multifamily Housing Pay for Success Program Narrative Template. [OGC–FH/Concurrence: When an SF is part of a HUD information collection request, it must be noted in the documentation because use of the SF will place a burden upon the respondents. Failure to include a required form in a new PRA package with the attended burden hours is legally insufficient. Recipients of federal financial assistance are required to submit assurances, including assurances that they will comply with federal civil rights requirements, as a condition of receiving an award of federal financial assistance. See *e.g.,* 24 CFR 1.5, 3.115, and 8.50. When OMB promulgated its government-wide grant making regulation, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 CFR part 200, it incorporated the assurances that were once contained in OMB Circular A–102 and the assurances contained in HUD's regulations into a standard form for agencies to use when obtaining such assurances. OMB's regulation specifically states that ''the Federal awarding agency must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements, including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination. The Federal awarding agency must communicate to the non-federal entity all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or in the terms and conditions of the Federal award.'' 2 CFR 200.200. Based on this requirement, HUD must ensure that that recipients are put on notice that the entire SF–424 Family, available at: *https://www.grants.gov/web/grants/forms/sf-424-individual-family.html,* including the SF–424B, and the SF–424D, as applicable, must be submitted. To ensure the PRA package is accurate, the reference to the SF–424 Family should be added to the PRA 60-day notice and supplemental information.]***

- Form HUD–2530, Previous Participation Certification, is completed by the Intermediary. The Intermediary submits the form to HUD via *grants.gov* as part of the application package for the PFS pilot. The type of information collected includes the Intermediary's (principals) Name, Address, Social Number/IRS Employee Number, Signature, etc. The form is required to provide HUD with a certified report of all previous participation in HUD multifamily housing projects by those parties making application and is used by HUD to determine eligibility to participate in Multifamily programs.
- ***SF–424 family of forms (SF–424A–D, as applicable), Application for Federal Assistance and Assurances, is completed by the Intermediary. The Intermediary submits this family of forms to HUD via *grants.gov* as part of the application for the PFS pilot. The type of information collected includes the Intermediary's Name, EIN/TIN, Address, Email address, etc. This family of forms is required for use as a cover sheet for submission of preapplications and applications and related information under discretionary programs. Applicants are required to submit this family of forms to HUD as part of the application package for the PFS pilot. [OGC–FH/Concurrence: As explained more fully in our comment above, all applicable forms in the SF–424 family are required to be submitted, including appropriate assurances. We have edited this paragraph to reflect this requirement.]***
- Form HUD–2880, Applicant/Recipient Disclosure/Update Report, is completed by the Intermediary. The Intermediary submits the from to HUD via the *grants.gov* as part of the application package for the PFS pilot. The type of information collected includes the Intermediary's Name, address, phone number, social security number and EIN, etc. The Intermediary is required to submit this form in order to provide accountability and integrity in the provision of assistance that is administered by HUD.
- Form HUD 424–CBW (excel spreadsheet), Detailed Budget Worksheet, is completed by the Intermediary. The Intermediary submits this form to HUD via email or U.S. mail for approval. The type of information collected includes a detailed description of budget as it pertains to each participating property. The Intermediary submits this form to HUD in program phases for completion of the retrofits in all participating properties in the PFS program.
- Form HUD–9250, Funds Authorization, is completed by the Owner. The Owner submits this form by email or by U.S. mail to HUD for approval. The type of information collected includes Owner's name, address, mortgagee, etc. Owners are required to submit this form to HUD to request withdrawal from the Reserve for Replacements or Residual Receipts Funds.
- Certification of Owner Eligibility, Owner must complete this form to be eligible to participate in the Pay for Success pilot. Owner submits certification to HUD for approval via email or by U.S. mail. The type of information collected includes Owner's name, iREMS number, address, signature, etc. Owners must provide a certification to HUD that they and the property meet HUD eligibility requirements in order to be able to participate in the Pilot.

• Cooperative Agreement is administered by HUD's Office of Multifamily Housing Programs, which will have oversight of the Intermediaries, ensuring compliance with all included provisions and authorizing payments when and if required conditions are met. The type of information collected includes Date agreement was entered with Intermediary, total of units HUD awarded intermediary, signature and HUD official. The form is submitted to HUD/Intermediary via email or by U.S. mail.

• Site-Specific Environment Review (Part 1 of 2), this form should be used only to initiate site-specific reviews for individual HUD-assisted properties undertaking energy and water conservation retrofits under the Multifamily Energy and Water Conservation Pay for Success Pilot. Intermediary completes the form and any relevant documents for each site identified to participate in the PFS Pilot and submits it to HUD to upload in the HUD Environmental Review Online System (HEROS).

• Office of Multifamily Housing Pay for Success Program Narrative Template is completed by the Intermediary and is submitted to HUD via *grants.gov*. The type of information collected includes the Intermediary's name, EIN, organization name, etc. The narrative template is provided to Applicants under the Pay for Success Pilot program and will be evaluated by HUD.

Description of the need for the information and proposed use: Title LXXXI of the Fixing America's Surface Transportation Act (Pub. L. 114–94) authorizes the Department of Housing and Urban Development (HUD) to establish a demonstration program under which the Secretary may execute budget-neutral, performance-based agreements in fiscal years 2016 through 2019 that result in a reduction in energy or water costs. The legislation authorizes HUD to implement this pilot in up to 20,000 units of multifamily buildings participating in the project-based rental assistance (PBRA) program under section 8 of the United States Housing Act of 1937; supportive housing for the elderly program operating under section 202 of the Housing Act of 1959; and supportive housing for persons with disabilities under section 811(d)(2) of the Cranston-Gonzalez National Affordable Housing Act. The Statute authorizes HUD to execute performance-based agreements in fiscal years 2016 through 2019 covering up to 20,000 units in eligible properties. HUD is responsible for submitting annual program evaluation reports to Congress for the duration of the Pilot.

HUD is authorized under this legislation to establish a competitive process for selecting one or more qualified applicants to serve as Intermediaries who will, per agreements with HUD, be responsible for initiating and managing an energy and water conservation retrofit program at eligible properties. For the purpose of this program, applicants are defined as entities applying to participate. The documents that are the subject of this notice are those used by applicants applying to participate in this program. This information will allow applicants to submit their proposal and for the government to evaluate this information.

I. ****Application.*** The applicants responding to the NOFA will need to submit before the prescribed deadline all standard forms including Previous Participation Certification (Form 2530), SF–424 family of forms, and Form HUD–2880; responses to the NOFA's rating factors describing the applicant's qualifications and proposed approach to all aspects of program implementation; and an Executive Summary of no more than four pages. [OGC–FH/Concurrence: As explained more fully in our comment above, all applicable forms in the SF–424 family are required to be submitted, including appropriate assurances. We have edited this paragraph to reflect this requirement.]***

II. *Project Initiation.* Once selected, Intermediaries will enter into a Cooperative Agreement with HUD for each property they will be retrofitting under the program which will provide for performance-based payments by HUD based on the savings realized by HUD after the retrofit has been completed. Intermediaries will also be required to submit a copy of an executed PFS Contracts with each property owner that will be attached to the Cooperative and serve to identify the specific units being affected by the retrofit. Within 30 days of entering into each Cooperative Agreement, an Intermediary will submit to HUD a Work Plan consisting of a description of all documentary deliverables and due dates related to that Agreement and a proposed approach to periodic consultation with HUD for the purposes of oversight. The Intermediary will also submit a request for approval for the Independent Evaluator that will be validating key information submitted to HUD by the Intermediary over the course of the Cooperative Agreement. Each participating property owner will submit to HUD a Certification of Eligibility and a written agreement to replace equipment installed under the PFS Pilot only with equipment of like or better efficiency.

III. *Retrofit implementation.* Before a retrofit is implemented, the Intermediary will develop and submit (with support from the property owner) a Site-specific Environmental Review form with the following information: High-level description of the project's scope of work; whether the property lies within a Coastal Barrier Resource unit; whether the property lies within a floodplain and proof of any required flood insurance policies; whether the project will destroy or modify a wetland; previous uses of the site and other evidence of contamination on or near the site; and whether any historic preservation policies apply to the site or the building(s). Intermediaries intending to use property-level reserve funds to pay for no more than half of the hard costs associated with the retrofit must submit a Scope of Work for the retrofit and a Reserve Analysis demonstrating that the retrofit will leave the property in as good or better financial shape as it would otherwise have been. The property owner must submit a Funds Authorization Form (HUD–9250) to request HUD's approval to use funds for this purpose.

IV. *Retrofit completion.* When the retrofit is completed, the Intermediary will submit a Certification of Retrofit Completion with the following information: A list of installed measures with cost information; weather- and occupancy-normalized pre-retrofit consumption baselines for each affected tenant- and owner-paid utility, and all component data used to calculate those baselines, including utility consumption, rates, utility allowances, and climatic and occupancy data, and the calculation methodology used; weather- and occupancy-normalized post-retrofit consumption projections for each affected tenant- and owner-paid utility, and all component data used to calculate those baselines, including utility consumption, rates, utility allowances, and climatic and occupancy data, and the calculation methodology used; recalculated pre-retrofit baseline utility allowances and post-retrofit utility allowances for each unit size/type; recalculated pre-retrofit baseline owner rental subsidy and post-retrofit owner renter for each unit size/type; and post-retrofit per-unit annual savings to HUD relative to pre-retrofit baseline.

V. *Performance payments.* Intermediaries will submit Invoices for Performance Payments concurrent with each property's annual rent adjustment cycle for the remainder of the period of

performance of the Cooperative Agreement pertaining to that property. Invoices will include thorough documentation of all calculations contributing to the calculation of the amount being invoiced (as provided in the work plan) as well as a written certification by the Independent Evaluator that the performance payment has been calculated according to the methodology contained in the Cooperative Agreement; no adverse changes to the qualifications of the Independent Evaluator have occurred since the last submission from the Independent Evaluator; and no conflict of interest or apparent conflict of interest exists with the Intermediary or with respect to any property or Owner which would preclude the Independent Evaluator from performing its obligations in a truly independent manner. In the event of a change in the physical structure of a property during the period of performance which materially impacts utility usage, the Owner and the Intermediary will mutually agree upon an equitable modification of the pre-retrofit baseline for Owner-paid utility and/or of the pre-retrofit baseline of tenant utility allowances to reflect the impact of the change on utility usage and notify HUD of the change. In the event that the Intermediary wishes to assign performance payments to a third party, the Intermediary must submit to HUD a written request for approval.

VI. *Other program administration requirements.* Beginning with the execution of their first cooperative agreement with HUD, Intermediaries will submit quarterly reports regarding the status of all properties for which work under the PFS Pilot is unfinished, including the work that has been completed, the work that remains the anticipated projected completion date. If at any point it becomes necessary to replace a partner entity performing one or more core functions program administration functions (project management, capital sources, oversight of SOW development and retrofit implementation, and/or invoicing HUD), the Intermediary must collect and submit evidence from the proposed replacement partner entity similar to the qualifications detailed for the original partner entity in the Intermediary's initial application. As this is pilot program and HUD is responsible for submitting annual program evaluation reports to Congress, Intermediaries may be required to work with a program evaluation team and provide relevant information, possibly including (but not limited to) information pertaining to retrofit implementation, program administration, post-retrofit behavioral interventions, and certain fees. Intermediaries may be asked to clarify or provide additional context for previously submitted information, including additional details on their sources and uses of funds.

Respondents (*i.e.,* affected public): Entities applying to be Intermediaries under this program, selected Intermediaries.

Estimated Number of Respondents: 15.

Estimated Number of Annual Responses: 1,000.

Frequency of Response: Varies.

Average Hours per Response: 10.8.

Total Estimated Annual Burden: 4,401.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: April 16, 2019.

Vance T. Morris,

Special Assistant to the Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2019–08366 Filed 4–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–12]

14-Day Notice of Emergency Approval of an Information Collection: The Housing Counseling Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, HUD has requested from the Office of Management and Budget (OMB) emergency approval of the information collection described in this notice.

DATES: Comments Due Date: May 9, 2019.

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*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

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. The **Federal Register** notice that solicited public comment on the information collection for a period of 14 days was published on April 25, 2019.

A. Overview of Information Collection

Title of Information Collection: Housing Counseling Program.

OMB Approval Number: 2502–0261.

Type of Request: Revision of currently approved collection.

Form Number: HUD 9902, HUD 9906, SF–424, HUD–424CB, SF–425, SF–LLL, HUD 2880.

Description of the need for the information and proposed use: This information is collected in connection with HUD's Housing Counseling Program and will be used by HUD to

determine that the Housing Counseling grant applicant meets the requirements of the Notice of Funding Availability (NOFA). Information collected is also used to assign points for awarding grant funds on a competitive and equitable basis. HUD's Office of Housing counseling will also use the information to provide housing counseling services through private or public organizations with special competence and knowledge in counseling low and moderate-income families. The information is collected from housing counseling agencies that participate in the HUD Housing Counseling Program. The information is collected via the HUD 9902 (grant activity report) and the form 9906 (grant application chart).

Respondents: Not-for-profit institutions.

Estimated Number of Respondents: 3,375.

Estimated Number of Responses: 9,900.

Frequency of Response: 2.93.

Average Hours per Response: 65.78.

Total Estimated Burdens: 651,229.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: April 17, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–08371 Filed 4–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2019–N029; FX3ES11130300000–189–FF03E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of Six Listed Animal and Plant Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews under the Endangered Species Act for two plant and four animal species. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information that has become available since the last review for the species.

DATES: To ensure consideration, please send your written information by June 24, 2019. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information for each species, see the table in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: To request information, contact the appropriate person in the table in the **SUPPLEMENTARY INFORMATION** section. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), for the Missouri bladderpod (*Physaria filiformis*), decurrent false aster (*Boltonia decurrens*), gray bat (*Myotis grisescens*), grotto sculpin (*Cottus specus*), Ozark hellbender (*Cryptobranchus alleganiensis bishop*), and purple cat's paw pearlymussel (*Epioblasma obliquata obliquata*).

Why do we conduct 5-year reviews?

Under the ESA, we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, go to *http://www.fws.gov/endangered/what-we-do/recovery-overview.html*, scroll down to ''Learn More about 5-Year Reviews,'' and click on our factsheet.

What information do we consider in our review?

A 5-year review considers the best scientific and commercial data that have become available since the current listing determination or most recent status review of each species, such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the ESA); and

(E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

New information will be considered in the 5-year review and ongoing recovery programs for the species.

What species are under review?

This notice announces our active 5-year status reviews of the species in the following table.

ANIMALS

Common name	Scientific name	Taxonomic group	Listing status	Where listed	Final listing rule (**Federal Register** citation and publication date)	Contact person, email, phone	Contact person's U.S. mail address
Missouri bladderpod ..	*Physaria filiformis*	Plant	T	MO	68 FR 59337; October 15, 2003.	Karen Herrington, *Karen_Herrington@fws.gov*; 573–234–2132.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Decurrent false aster	*Boltonia decurrens* ..	Plant	T	IL, MO	53 FR 43858; November 14, 1988.	Kristen Lundh; *Kristen_Lundh@fws.gov*; 309–757–5800.	USFWS, 1511 47th Avenue, Moline, IL 61265.
Gray bat	*Myotis grisescens* ...	Mammal	E	AL, AR, FL, GA, IL, IN, KA, KY, MO, OK, TN, VA, WV.	41 FR 17736; April 28, 1975.	Shauna Marquardt; *Shauna_Marquardt@fws.gov*; 573–234–2132.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Grotto sculpin	*Cottus specus*	Fish	E	MO	78 FR 58938; September 25, 2013.	Laurel Hill; *Laurel_Hill@fws.gov*; 573–234–2132.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Ozark hellbender	*Cryptobranchus alleganiensis bishop.*	Amphibian	E	AR, MO	76 FR 61956; October 6, 2011.	Trisha Crabill; *Trisha_Crabill@fws.gov*; 573–234–2132.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Purple cat's paw pearlymussel.	*Epioblasma obliquata obliquata.*	Clam	E	OH	55 FR 28209; July 10, 1990.	Angela Boyer; *Angela_Boyer@fws.gov*; 614–416–8993.	USFWS, 4625 Morse Road, Suite 104, Columbus, OH 43230.

Request for Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See *What Information Do We Consider in Our Review?* for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

If you wish to provide information for any species listed above, please submit your comments and materials to the appropriate contact in the table above. You may also direct questions to those contacts. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Submissions

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.

Comments and materials received will be available for public inspection, by appointment, during normal business hours at the offices where the comments are submitted.

Authority

We publish this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2019–08318 Filed 4–24–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X21109AF LLUT92000 L13100000 FI0000 25–7A]

Notice of Proposed Class II Reinstatement of Terminated Oil and Gas Lease UTU87659, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with Mineral Leasing Act of 1920 as Amended, Flatirons Resources LLC filed a timely petition for reinstatement of oil and gas lease UTU87659 for lands in Grand County, Utah. The petition was accompanied by all required rentals and royalties accruing from January 1, 2016, the date of termination. No leases were issued that affect these lands. The Bureau of Land Management proposes to reinstate this lease.

FOR FURTHER INFORMATION CONTACT: Kent Hoffman, Deputy State Director, Lands and Minerals, Utah State Office, Bureau of Land Management, 440 West 200 South, Suite 500, Salt Lake City, Utah, 84101, phone (801) 539–4063, Email: *khoffman@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee has agreed to the new lease terms:

- Original term and conditions of the lease;
- Increased rental of $10 per acre;
- Increased royalty of 16-2/3 percent;
- $159 cost of publishing this Notice; and
- $500 cost of administrative fee.

The lease includes the following described lands in Grand County, Utah:

UTU87659

Salt Lake Meridian, Utah

T. 19 S, R 25 E,
Sec. 3, lots 1 to 3, S1/2NE1/4, SE1/4NW1/4, NE1/4SW1/4, SE1/4;

Sec. 4, lots 1 to 2, S1/2NE1/4, SE1/4;
Sec. 10, NE1/4NW1/4.

The area described contains 802.31 acres.

The lessee has met all the requirements for reinstatement of the lease per Section 31(d) and (e) of the Mineral Leasing Act of 1920 as Amended. The BLM is proposing to reinstate the lease 30 days following publication of the notice, with the effective date of January 1, 2016, subject to the:

Authority: 43 CFR 3108.2–3.

Edwin L. Roberson,

State Director.

[FR Doc. 2019–08342 Filed 4–24–19; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–013]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: May 1, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. *Minutes.*
3. *Ratification List.*
4. *Vote on Inv. Nos.* 701–TA–601 and 731–TA–1411 (Final) (Laminated Woven Sacks from Vietnam). The Commission is currently scheduled to complete and file its determinations and views of the Commission by May 28, 2019.
5. *Outstanding action jackets:* None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: April 22, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–08458 Filed 4–23–19; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0014]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Application for Tax Paid Transfer and Registration of Firearm—ATF Form 4 (5320.4)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 1140–0014 (Application for Tax Paid Transfer and Registration of Firearm—ATF Form 4 (5320.4)), is being revised to accommodate additional questions, include definition of new terminology, and changes to the instructions.

DATES: Comments are encouraged and will be accepted for 60 days until June 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Chancey, National Firearms Act Division either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *nfaombcomments@atf.gov,* or by telephone at 304–616–4594.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of This Information Collection

1. *Type of Information Collection* (check justification or form 83): Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Tax Paid Transfer and Registration of Firearm.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 4 (5320.4).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households, Businesses or other for-profit, Federal Government and State, Local or Tribal Government.

Other (if applicable): Not-for-profit institutions.

Abstract: The ATF Form 4 (5320.4) is filed to obtain permission to transfer and register a National Firearms Act (NFA) firearm. A transfer without approval and possession of an unregistered NFA firearm are illegal. The approval of the application effectuates the registration of a firearm to the transferee. There is a tax of $5 or $200 on the transfer of an NFA firearm with certain exceptions (see ATF Forms 3 and 5 for tax-exempt transfer information).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 123,339 respondents will utilize the form, and it will take each respondent approximately 227.0598 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 466,775 hours, which is equal to 123,339 (# of respondents) * 1 (# of responses per respondents) * 3.78433 hours (227.0598 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–08314 Filed 4–24–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0015]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Application for Tax Exempt Transfer and Registration of Firearm—ATF Form 5 (5320.5)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection OMB 1140–0015 (Application for Tax Exempt Transfer and Registration of Firearm—ATF Form 5 (5320.5)), is being revised due to material changes to the form, including additional questions, definition of terminology used in the collection instrument, and updates to the instructions.

DATES: Comments are encouraged and will be accepted for 60 days until June 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Chancey, National Firearms Act Division either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *nfaombcomments@atf.gov,* or by telephone at 304–616–4594.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of This Information Collection

1. *Type of Information Collection* (check justification or form 83): Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Tax Exempt Transfer and Registration of Firearm.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5 (5320.5).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Federal Government and State, Local or Tribal Government.

Other (if applicable): Individuals or households, Business or other for-profit, Not-for-profit institutions, and Farms.

Abstract: The ATF Form 5 (5320.5) is required for a person with a registered National Firearms Act (NFA) (Title 26, United States Code, Chapter 53) firearm to apply for permission to transfer and register an NFA firearm. The statutory requirements are implemented in Title 27, Code of Federal Regulations, Part 479. Approval of the application effectuates the registration of a firearm to the transferee. The transferee claims an exemption from the transfer tax by filing this application.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 10,591 respondents will utilize the form, and it will take each respondent approximately 30.309 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 5,350 hours, which is equal to 10,591 (# of respondents) * 1 (# of responses per respondents) * .5052 hours (30.309 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–08315 Filed 4–24–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0011]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Application To Make and Register a Firearm—ATF Form 1 (5320.1)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection OMB 1140–0011 (Application to Make and Register a Firearm—ATF Form 1 (5320.1)), is being revised to include formatting changes, additional questions, and updates to the instructions.

DATES: Comments are encouraged and will be accepted for 60 days until June 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Chancey, National Firearms Act Division either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *nfaombcomments@atf.gov,* or by telephone at 304–616–4594.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of This Information Collection

1. *Type of Information Collection* (check justification or form 83): Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application to Make and Register a Firearm.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 1 (5320.1).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households, Business or other for-profit, Federal Government and State, Local or Tribal Government.

Other (if applicable): Farms and Not-for-profit.

Abstract: The ATF Form 1 (5320.1) is required obtain permission to make and register a National Firearms Act (NFA) firearm. Possession of an unregistered NFA firearm is illegal. The approval of the application effectuates the registration of the firearm to the applicant. For any person other than a government agency, the making incurs a tax of $200.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 25,716 respondents will utilize the form one (1) time, and it will take each respondent approximately 239.9 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 102, 808 hours, which is equal to 25,716 (# of respondents) * 3.99783 hours (239.9 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–08317 Filed 4–24–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0107]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; National Firearms Act (NFA) Responsible Person Questionnaire—ATF Form 5320.23

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection OMB 1140–0107 (National Firearms Act (NFA) Responsible Person Questionnaire—ATF Form 5320.23), is being revised to include additional questions and updates to the instructions including definition of new terminology.

DATES: Comments are encouraged and will be accepted for 60 days until June 24, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Chancey, National Firearms Act Division either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *James.Chancey@atf.gov,* or by telephone at 304–616–4594.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* National Firearms Act (NFA) Responsible Person Questionnaire.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5320.23.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit, Federal Government. State, Local or Tribal Government.

Other (if applicable): Individuals or households. Not-for-profit institutions and Farms.

Abstract: The ATF Form 5320.23 is required for any responsible person (as defined in 27 CFR 479.11) who is part of a trust or legal entity that is applying on ATF Form 1, Application to Make and Register a Firearm, as the maker or is identified as the transferee on ATF Form 4, Application for Tax Paid Transfer and Registration of Firearm, or ATF Form 5, Application for Tax Exempt Transfer of Firearm. Forms 1, 4 and 5 are required under the National Firearms Act (NFA).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 115,829 respondents will utilize the form and it will take each respondent approximately 30 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 57,914.5 or 57,915 hours, which is equal to 115,829 (# of respondents) * 1 (# of responses per respondents) * .5 (30 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 19, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–08316 Filed 4–24–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. The Walt Disney Company, et al.; Response to Public Comment

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that one comment was received concerning the proposed Final Judgment in this case, and that comment together with the Response of the United States to Public Comment have been filed with the United States District Court for the Southern District of New York in *United States of America* v. *The Walt Disney Company, et al.,* Civil Action No. 1:18-cv-5800 (CM). Copies of the comment and the United States' Response are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the Southern District of New York. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Patricia A. Brink,

Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

United States of America, Plaintiff, v. *The Walt Disney Company,* and *Twenty-First Century Fox, Inc.,* Defendants.

18 Civ. 5800 (CM) (KNF)

RESPONSE OF PLAINTIFF UNITED STATES TO PUBLIC COMMENT ON THE PROPOSED FINAL JUDGMENT

Pursuant to the requirements of the Antitrust Procedures and Penalties Act (the ''APPA'' or ''Tunney Act''), 15 U.S.C. § 16(b)–(h), the United States hereby responds to the one public comment received regarding the proposed Final Judgment in this case. After careful consideration of the submitted comment, the United States continues to believe that the proposed Final Judgment will provide an effective and appropriate remedy for the antitrust violations alleged in the Complaint. The United States will move the Court for entry of the proposed Final Judgment after the public comment and this response have been published pursuant to 15 U.S.C § 16(d).

I. PROCEDURAL HISTORY

On December 13, 2017, The Walt Disney Company (''Disney'') entered into an agreement to acquire certain assets and businesses from Twenty-First Century Fox, Inc. (''Fox'') (collectively, ''Defendants''), including Fox's ownership of, or interests in, its regional sports networks (''RSNs''), FX cable networks, National Geographic cable networks, television studio, Hulu, film studio, and international television businesses (collectively, the ''Fox Sale Assets''). On June 20, 2018, the Defendants amended the agreement to increase Disney's consideration for the Fox Sale Assets to approximately $71.3 billion. On July 27, 2018, Disney's and Fox's respective shareholders voted to approve the transaction.

On June 27, 2018, the United States filed a civil antitrust Complaint, seeking to enjoin Disney from acquiring the Fox Sale Assets. The Complaint alleges that the proposed acquisition by Disney of certain cable sports programming assets from Fox, including Fox's ownership of, or interest in, twenty-two RSNs, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment and a Hold Separate Stipulation and Order signed by Plaintiff and Defendants consenting to entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act, 15 U.S.C. § 16. Pursuant to those requirements, the United States filed a Competitive Impact Statement (''CIS'') on August 7, 2018, describing the transaction and the proposed Final Judgment. The United States published the Complaint, proposed Final Judgment, and CIS in the **Federal Register** on August 15, 2018, *see* 83 Fed. Reg. 40,553 (2018), and caused summaries of the proposed Final Judgment and CIS, together with directions for the submission of written comments related to the proposed Final Judgment, to be published in *The Washington Post* and *The New York Times* for seven days, from August 13, 2018 through August 19, 2018. The 60-day public comment period required by the Tunney Act, 15 U.S.C. § 16(b) and (d), ended on October 18, 2018. The United States received one comment concerning the allegations in the Complaint (Exhibit 1).[1]

[1] In addition to the one comment, the United States also received an email from an individual based in Bangalore, India on the proxy voting procedure by which Disney and Fox shareholders approved the transaction. *See* Exhibit 2. This email is unrelated to the competitive concerns identified by the United States in the Complaint, and it is unrelated to the issue before this Court: whether the proposed Final Judgment is in the public interest. It is well-settled that comments that are unrelated to the concerns identified in the Complaint are beyond the scope of the court's Tunney Act review. *See, e.g., United States v. Apple*, Inc., 889 F. Supp.

Continued

II. THE COMPLAINT AND THE PROPOSED FINAL JUDGMENT

The Complaint alleged that Disney's acquisition of the Fox RSNs would lessen competition in the licensing of cable sports programming to distributors in local markets where Disney and Fox compete. The proposed Final Judgment remedies this concern by requiring Disney to divest the twenty-two Fox RSNs it would have acquired as part of the Fox Sale Assets.

Disney's acquisition of the Fox Sale Assets would have combined two of the most valuable cable sports television networks: Fox's twenty-two RSNs and Disney's ESPN franchise of networks. Cable sports television networks compete to be carried in the programming packages that distributors, such as cable companies (e.g., Charter Communications and Comcast), direct broadcast satellite services (e.g., DISH Network and AT&T's DirecTV), fiber optic networks services (e.g., Verizon's Fios and CenturyLink's Prism TV), and online distributors of linear cable programming (e.g., Hulu Live and DISH's Sling TV), offer to their subscribers. For RSNs, the carriage license typically is limited to the Designated Market Area (''DMA'') comprising the ''home'' territory of the team or teams carried on the RSN; whereas, licenses for national television networks, such as ESPN, typically comprise all DMAs in a distributor's footprint. Disney's and Fox's cable sports television programming compete head-to-head to be carried by distributors in each DMA that is the home territory of Fox's RSNs: Phoenix, AZ; Los Angeles, CA; San Diego, CA; Miami, FL; Orlando, FL; Tampa, FL; Atlanta, GA; Indianapolis, IN; Kansas City, KS; New Orleans, LA; Detroit, MI; Minneapolis, MN; St. Louis, MO; New York, NY; Charlotte, NC; Raleigh-Durham, NC; Cincinnati, OH; Cleveland, OH; Columbus, OH; Oklahoma City, OK; Nashville, TN; Memphis, TN; Dallas, TX; San Antonio, TX; and Milwaukee, WI (collectively, the ''DMA Markets'').

After Disney announced its plans to acquire the Fox Sale Assets, the United States conducted an investigation into the competitive effects of the proposed transaction. The United States considered the potential competitive effects of the transaction on cable sports programming in DMAs throughout the United States. As a part of its investigation, the United States obtained documents and information from the merging parties and others and conducted interviews with customers, competitors, and other individuals knowledgeable about the industry.

Based on the evidence gathered during its investigation, the United States concluded that Disney's acquisition of Fox's RSNs would likely (1) substantially lessen competition in the licensing of cable sports programming in each of the DMA Markets; (2) eliminate actual and potential competition among Disney and Fox in the licensing of cable sports programming in each of the DMA Markets; and (3) cause prices for cable sports programming in each of the DMA Markets to increase.

At the same time the Complaint was filed, the United States filed a Hold Separate Stipulation and Order (''Hold Separate'') and proposed Final Judgment, which are designed to eliminate the likely anticompetitive effects of the Transaction. Under the proposed Final Judgment, Disney is required to divest all of Fox's interests in the Fox RSNs, including all assets necessary for the operation of each Fox RSN as a viable, ongoing cable sports programming network, to one or more buyers acceptable to the United States in its sole discretion. Under the terms of the Hold Separate, Disney and Fox have taken certain steps to ensure that each Fox RSN continues to operate as an ongoing, economically viable, competitive cable sports programming network that will remain independent and uninfluenced by the consummation of the Transaction, and that competition is maintained during the pendency of the ordered divestiture.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof. Nothing in the APPA or the parties' filings in this case prohibit Defendants from closing and consummating the Transaction during the pendency of the Tunney Act proceedings or prior to the Court's entry of the proposed Final Judgment. *See* 15 U.S.C. § 16(b)–(h).

III. STANDARD OF JUDICIAL REVIEW

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States v. Keyspan Corp.*, 763 F. Supp. 2d 633, 637–38 (S.D.N.Y. 2011); *see SEC v. Citigroup Global Markets Inc.*, 673 F.3d 158, 168 (2d Cir. 2012) (''We are bound in such matters to give deference to an executive agency's assessment of the public interest.''). *See generally United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public-interest standard under the Tunney Act); *United States v. U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable'').

As this Court has held, under the APPA a court considers, among other things, ''the relationship between the complaint and the remedy secured, the decree's clarity, whether there are any

2d 623, 642 (S.D.N.Y. 2012); *United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1, 14 (D.D.C. 2007) (quoting *United States v. Microsoft Corp.*, 56 F.3d 1448, 1459 (D.C. Cir. 1995)); *see also United States v. U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 76 (D.D.C. 2014) (quoting *Microsoft*, 56 F.3d at 1459).

foreseeable difficulties in implementation, and whether the decree might positively injure third parties.'' *United States v. Apple, Inc.*, 889 F. Supp. 2d 623, 631 (S.D.N.Y. 2012) (citing *Microsoft*, 56 F.3d at 1458, 1461–62). With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft*, 56 F.3d at 1460–62; *Apple*, 889 F. Supp. 2d at 631. Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2]

In determining whether a proposed settlement is in the public interest, a district court ''is not permitted to reject the proposed remedies merely because the court believes other remedies are preferable.'' *United States v. Morgan Stanley*, 881 F. Supp. 2d 563, 567 (S.D.N.Y. 2012) (quoting *United States v. Abitibi–Consol. Inc.*, 584 F. Supp. 2d 162, 165 (D.D.C. 2008)); *SBC Commc'ns*, 489 F. Supp. 2d at 17 (''[a district court] must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations''); *see also U.S. Airways*, 38 F. Supp. 3d at 74–75 (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant ''due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case''). The ultimate question is whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft*, 56 F.3d at 1461. To meet this standard, the United States need only provide ''a factual foundation for the government's decisions such that its conclusions regarding the proposed settlement are reasonable.'' *Morgan Stanley*, 881 F. Supp. 2d at 567 (quoting *Abitibi–Consol.*, 584 F. Supp. 2d at 165); *see also SBC Commc'ns*, 489 F. Supp. 2d at 17.

Moreover, under *Microsoft*, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft*, 56 F.3d at 1459; *United States v. Keyspan Corp.*, 763 F. Supp. 2d 633 637-38 (S.D.N.Y. 2011) (''The Court's function is not to determine whether the proposed [d]ecree results in the balance of rights and liabilities that is the one that will best serve society, but only to ensure that the resulting settlement is 'within the reaches of the public interest.''' (quoting *United States v. Alex. Brown & Sons, Inc.*, 963 F. Supp. 235, 238 (S.D.N.Y. 1997))); *see also InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60; *see also United States v. Fokker Servs.*, 818 F.3d 733, 738 (D.C. Cir. 2016) (recognizing the ''long-settled understandings about the independence of the Executive with regard to charging decisions''); *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (quoting U.S. Const. art. II, § 3) (recognizing that the decision about which claims to bring ''has long been regarded as the special province of the Executive Branch.'').

Finally, in the 2004 amendments to the APPA, Congress addressed the Tunney Act review process, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns*, 489 F. Supp. 2d at 11; *see also Apple*, 889 F. Supp. 2d at 632. A court can make its public-interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways*, 38 F. Supp. 3d at 76; *see also United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); S. Rep. No. 93-298 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

IV. PUBLIC COMMENT AND THE UNITED STATES' RESPONSE

During the 60-day comment period, the United States received only one comment from the American Cable Association (''ACA''), an organization that represents more than 700 small and medium-sized cable operators (Exhibit 1). Upon review, the United States believes that nothing in the comment warrants a change to the proposed Final Judgment or supports an inference that the proposed Final Judgment is not in the public interest. As required by the APPA, the comment and the United

[2] *See also BNS*, 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

States' response will be published in the **Federal Register**.

In its comment, the ACA commends the proposed Final Judgment, noting that it ''solves one significant antitrust problem . . . by requiring Disney to divest the Fox RSNs.'' Exhibit 1 at 1. However, it warns that a divestiture to a same-market, big-four broadcaster or a same-market distributor ''threatens to create a *new* and equally significant antitrust problem.'' *Id.* While noting that the proposed Final Judgment gives the United States sole discretion to determine that the divestiture will preserve competition in the relevant markets, *id.* at 2; *see* Proposed Final Judgment, *United States v. The Walt Disney Co.*, 1:18-cv-5800 at IV.J (S.D.N.Y. June 27, 2018), the ACA requests the Final Judgment to be modified to expressly prohibit divestitures to a same-market broadcaster or same-market distributor. Exhibit 1 at 2.

The United States considers the existing terms of the proposed Final Judgment—which require the sale of the Fox RSNs ''to one or more Acquirers acceptable to the United States, in its sole discretion,'' Proposed Final Judgment, *Disney*, 1:18-cv-5800 at IV.A—sufficient to ensure that competition will be preserved in all affected markets. In exercising its sole discretion to approve buyers, the United States has a duty to ensure that the remedy addresses the harm arising from the merger and preserves competition. The Antitrust Division employs three fundamental tests when reviewing proposed divestiture buyers: 1) divestiture of the assets to the proposed purchaser must not itself cause competitive harm, 2) the Division must be certain that the purchaser has the incentive to use the divestiture assets to compete in the relevant market, and 3) the Division will perform a ''fitness'' test to ensure that the purchaser has sufficient acumen, experience, and financial capability to compete effectively in the market over the long term. As required by the first fundamental test, the Antitrust Division will review whether divesting the Fox RSNs to Disney's proposed buyer(s) would itself cause competitive harm. Moreover, the second and third fundamental tests go further—requiring the Antitrust Division to assess both the incentive and ability of the buyer to actively compete with the Fox RSNs.

The Court should reject the ACA's invitation to substitute its judgment for the United States' judgment of the acceptability of divestiture buyers and the overall effect of the divestitures on competition. Approving divestiture buyers is the type of action that is properly within the United States' discretion. S*ee InBev N.V./S.A.*, 2009 U.S. Dist. LEXIS 84787 at *23 (questioning the court's role in monitoring the reasonableness of the United States' approval of a divestiture buyer); *Morgan Stanley*, 881 F. Supp. 2d at 568; *Microsoft*, 56 F.3d at 1461; *Citigroup Global Markets, Inc.*, 673 F.3d at 163–64. ACA cites no legal basis for its proposed restriction of the United States' discretion. Nor does the ACA claim that the factual foundation underpinning the proposed Final Judgment renders the proposed settlement unreasonable. *See* Exhibit 1. In Tunney Act proceedings, courts routinely enter final judgments that provide the United States with the sole discretion to assess the acceptability of divestiture buyers. *See, e.g.*, Final Judgment, *United States v. Marquee Holdings, Inc.*, 5-cv-10722 (S.D.N.Y. Jan. 9, 2006); Final Judgment, *United States v. AMC Entertainment Holdings, Inc.*, 16-cv-2475-RDM (D.D.C. Mar. 7, 2017); Final Judgment, *United States v. United Technologies Corp.*, 1:12-cv-1230-KBJ (D.D.C. May 29, 2013); Final Judgment, *United States v. Dean Foods Co.*, 10-cv-59 (E.D. Wis. July 29, 2011); Final Judgment, *United States v. AT&T Inc.*, 1:09-cv-1932-HHK (D.D.C. Feb. 10, 2010); Final Judgment, *United States v. Sony Corp. of America*, 98-cv-2716 (S.D.N.Y. Nov. 16, 1998). There is no justification here to depart from the ordinary course and fetter the United States' discretion.

CONCLUSION

After reviewing the public comment, the United States continues to believe that the proposed Final Judgment, as drafted, provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the comment and this response are published in the **Federal Register**.

Dated: April 5, 2019

Respectfully submitted,

Lauren G.S. Riker,
United States Department of Justice, Antitrust Division, 450 Fifth Street NW, Suite 4000, Washington, DC 20530, Tel: 202–598–2812, Lauren.Riker@usdoj.gov.
Counsel for the United States

EXHIBIT 1 TO RESPONSE

HWG | Harris, Wiltshire & Grannis LLP

October 15, 2018

BY ELECTRONIC MAIL

Owen M. Kendler, Esq., Chief, Media, Entertainment, and Professional Services Section Antitrust Division, Department of Justice, Washington, DC 20530,
atr.mep.information@usdoj.gov

Re: ACA Tunney Act Comments on *United States v. Walt Disney* Proposed Final Judgment

Dear Mr. Kendler:

The American Cable Association, which represents more than 700 small and medium-sized cable operators, hereby submits its Tunney Act comments regarding the proposed Final Judgment filed in *United States v. Walt Disney*.[3] The proposed Final Judgment solves one significant antitrust problem—the combination of Disney's ESPN with Fox's regional sports networks (''RSNs'')—by requiring Disney to divest the Fox RSNs. Such divestiture, however, threatens to create a *new* and equally significant antitrust problem.[4]

More specifically, it would be contrary to the public interest to permit the divestiture of the Fox RSNs either to a same-market, big-four broadcaster or to a same-market multichannel video programming distributor (''MVPD''):

- Permitting such a broadcaster to purchase a Fox RSN would create the very problem the Antitrust Division identified here. It would allow a single firm to threaten to withhold two sets of must-have programming, thereby leading to increased MVPD licensing fees.
- Permitting such an MVPD to purchase an RSN would create the ''vertical integration'' problem the Division identified in blocking the AT&T-Time Warner merger. The combined entity would have greater leverage to threaten to withhold RSN programming from rival MVPDs than would a stand-alone RSN owner, thereby leading to increased MVPD licensing fees.

The proposed Final Judgment already provides the Division with the ''sole discretion'' [5] to approve a divestiture

[3] Antitrust Procedures and Penalties Act 15 U.S.C. § 16(b)–(h); *United States v. Walt Disney Co.*, Proposed Final Judgment and Competitive Impact Statement, 83 Fed. Reg. 40553 (rel. Aug. 15, 2018) (''*Proposed Final Judgment*'').

[4] *See* Antitrust Division Policy Guide to Merger Remedies at 28 (describing as a ''fundamental test[]'' of divestiture approval that the ''divestiture of the assets to the proposed purchaser [does] not itself cause competitive harm.'').

[5] *Proposed Final Judgment*, 83 Fed. Reg. at 40557 § IV.A (requiring Fox to divest its RSNs ''in a manner consistent with this Final Judgment to one or more Acquirers acceptable to the United States, in its sole discretion'').

party for Fox's RSNs. But the Final Judgment should make clear beforehand that the Division will not permit any divestiture to a same-market broadcaster or same-market MVPD. A settlement permitting any such divestiture would not be in the public interest.

I. The Division Should Not Permit Disney to Divest Fox's RSNs to a Same-Market Broadcaster.

The Competitive Impact Statement described the problem that an ACA member would face in negotiating with a newly combined ESPN-Fox RSN—losing both sets of programming simultaneously is far worse than losing each set of programming individually:

Prior to the Transaction, an MVPD's failure to reach a licensing agreement with Disney would result in the blackout of Disney's networks, including ESPN, and threaten some subscriber loss for the MVPD, including those subscribers that value ESPN's content. But because the MVPD still would be able to offer its subscribers the local Fox RSN, many MVPD subscribers simply would watch the local RSN instead of cancelling their MVPD subscriptions. In the event of a Fox RSN blackout, many subscribers likely would switch to watching ESPN. After the Transaction, an MVPD negotiating with Disney would be faced with the prospect of a dual blackout of significant cable sports programming, a result more likely to cause the MVPD to lose incremental subscribers (that it would not have lost in a pre-transaction blackout of only ESPN or the Fox RSN) and therefore accede to Disney's demand for higher licensing fees. For these reasons, the loss of competition between ESPN and the Fox RSN in each DMA Market would likely lead to an increase in MVPD licensing fees in those markets. Some of these increased programming costs likely would be passed onto consumers, resulting in higher MVPD subscription fees for millions of U.S. households.[6]

An ACA member would face this exact problem in negotiating simultaneously with a Fox RSN and a same-market, big-four broadcaster,[7] which invariably controls sports rights at least as important as those controlled by ESPN. Absent the combination, failure to reach an agreement with the RSN would result in some subscriber loss—but other subscribers would watch the broadcaster's programming instead. With the combination, the ACA member would be faced with the prospect of a dual blackout, making it more likely that it would lose incremental subscribers.[8] It would thus be more likely to accede to demands for higher fees. This may be because the broadcaster's sports programming constitutes a partial substitute for the RSN's programming—a conclusion not inconsistent with the Division's original conclusion that broadcast programming is not a *sufficiently strong* substitute to prevent harms from the Fox RSN-ESPN combination.[9] Or it may be true regardless of substitutability.[10] Regardless of the theory, the best empirical analysis, conducted by the FCC's economists, suggests that RSN-broadcast combinations lead to higher prices.[11] The Final Judgment should reflect that fact here.

II. The Division Should Not Permit Disney to Divest Fox's RSNs to a Same-Market MVPD.

While divestiture of Fox's RSNs to a broadcaster would replicate the problem that the Division identified in *this* proceeding, divestiture to a same-market MVPD[12] would replicate the problem the Division identified in seeking to block the AT&T-Time Warner merger—a *vertical* combination of Fox's RSN programming and MVPD distribution will lead to price increases.[13] Here is how the government explained its concerns about vertical integration:

Pre-merger, a blackout of Turner programming on Charter (for example) cost Time Warner license fees from Charter and advertising revenue from reduced viewership, and it cost Charter current and potential customers because its service is less attractive without the desirable Turner programming. Crucially, post-merger, that same blackout is less costly to AT&T than it had been to Time Warner alone because some Charter subscribers will switch to AT&T's DirecTV or UVerse. . . . It is precisely because of this diversion to DirecTV (which would have the competitively valuable Turner content) that the costs of blackouts to the merged entity would be lower than absent the merger. Because—solely as a result of the merger—the costs of not reaching a deal are reduced, Time Warner will have increased leverage to negotiate better terms with rival distributors. Exercising that leverage will result in increased programming fees for those rival distributors—lessening competition among DirecTV and its rivals—and ultimately increasing prices for millions of American consumers.[14]

So too if Fox RSNs are divested to a same-market MVPD.[15] Today, if Fox fails to reach agreement with an ACA member, it loses license fees and advertising revenue. If combined with an MVPD that competes with the ACA member, however, the calculus changes. The *RSN* loses license fees from the ACA member and advertising revenue. But the *competing MVPD* gains new fees from subscribers who switch to it from the ACA member in order to retain their

[6] *Id.*, 83 Fed. Reg. at 40564 § B.2.

[7] By ''same-market broadcaster,'' we refer to a television station located in a designated market area served by the RSN at issue. Thus, for example, WTTG-5 is in the Washington DC DMA, which is also served by Comcast's NBC SportsNet Washington, an RSN. So WTTG would be a ''same-market broadcaster'' with respect to NBC SportsNet Washington. (Please note that RSNs often cover multiple markets. NBC SportsNet Washington, for example, covers both Washington and Baltimore. So WBFF-45 in Baltimore would be a ''same market broadcaster'' with respect to NBC SportsNet Washington as well.) By ''big four'' broadcaster, we refer to stations affiliated with the ABC, NBC, CBS, and FOX networks, each of which offers ''must have'' sports programming.

[8] We note that Sinclair appears to have expressed interest in obtaining Fox's RSNs. Gerry Smith, *Sinclair Considers Tapping Private Equity to Buy Fox Sports Networks,* Bloomberg (Oct. 2, 2018), *available at https://www.bloomberg.com/news/articles/2018-10-02/sinclair-mulls-tapping-private-equity-to-buy-fox-sports-networks.* By our calculations, Sinclair's broadcast stations overlap Fox's RSNs to a greater extent than do Fox's own broadcast stations.

[9] *Proposed Final Judgment,* 83 Fed. Reg. at 40563 § II.B.

[10] For example, it may be that increased size permits a broadcaster to claim a larger share of the joint gains from agreement—what economists call ''bargaining power'' or ''bargaining skill.'' Or it may be that MVPDs are risk averse, and their marginal disutility from lost income increases in the amount of income lost. Or, in certain circumstances, combining negotiations for two sets of ''must-have'' programming could make the demand for each type of programming less sensitive to price. *See, e.g.,* Comments of the American Cable Association at 26 *et seq.* and Attachment 1, FCC Docket No. 15-216 (filed Dec. 1, 2015) (containing submission by Michael H. Riordan, Professor of Economics at Columbia University).

[11] *See Comcast Corporation, General Electric Company and NBC Universal, Inc.*, 26 FCC Rcd. 4238, ¶ 137 (2011) (finding that ''an analysis of the relevant data, presented in the Technical Appendix, suggests that joint ownership of an RSN and broadcast station in the same region may lead to substantially higher prices for the jointly owned programming relative to what would be observed if the networks were under separate ownership'').

[12] By ''same-market MVPD,'' we mean an MVPD offering service within the RSN's service area. Please note that AT&T and DISH both provide service nationwide, and would thus be ''same-market MVPDs'' with respect to all Fox RSNs.

[13] The Division has identified this concern previously. *See United States v. Comcast Corp.*, No. 11-cv-00106 (D.D.C. 2011), § II.D.2.A. So too has the Federal Communications Commission. *See, e.g., Adelphia Commc'n Corp., and Time Warner Cable,* 21 FCC Rcd. 8203, ¶¶ 122-65 (2006) (''*Adelphia Order*'').

[14] Proof Brief of Appellant at 33-34, *United States v. AT&T Inc.*, No. 17-2511 (D.C. Cir. 2018).

[15] *See* Mike Farrell, ''It's Game On for Fox RSN Sell-Off,'' Multichannel News (Aug. 28, 2018) (listing as potential suitors John Malone; Liberty Media; Madison Square Garden's ruling Dolan family or Dolan-controlled entities such as MSG Networks; AT&T; Verizon; and Comcast), *available at https://www.multichannel.com/news/its-game-on-for-fox-rsn-sell-off.*

RSN programming. There is, in other words, a ''silver lining'' for the combined RSN/MVPD if it fails to reach a deal. This gives the combined entity additional leverage—which means that prices will increase.[16]

Of course, as the *AT&T-Time Warner* litigation has made clear, a key factor in determining the magnitude of concern about vertical integration is the so-called ''diversion rate''—that is, how many subscribers will switch providers in order to retain particular programming. This, in turn, depends on the importance of the programming itself. In this regard, we would note that the *AT&T-Time Warner* merger did not involve RSNs at all. And the Federal Communications Commission has considered RSNs paradigmatic ''must have'' programming—the kind of programming for which subscribers will switch providers—for at least fifteen years.[17] Vertical integration involving RSNs, in other words, should concern the Division at least as much as does any other type of vertical integration.

* * * * *

Again, we very much appreciate the Division's efforts to address concerns related to the combination of Fox's RSN assets and Disney's ESPN.[18] But it would not be in the public interest to permit the divestiture of Fox's RSNs to a same-market, big-four broadcaster or to a same-market MVPD. Moreover, since the antitrust problems raised by these kind of divestitures are evident before the fact, the Division need not expend the resources to examine such divestitures individually or after the fact.

Respectfully submitted,
Michael Nilsson
Mark Davis
Counsel to the American Cable Association

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[16] *See* Amicus Brief of William Rogerson and the American Cable Association at 11-12, *United States v. AT&T Inc.*, No. 17-2511 (D.C. Cir. 2018).

[17] *Gen. Motors Corp. & Hughes Elecs. Corp.*, 19 FCC Rcd. 473, ¶ 147 (2004); *News Corp., DIRECTV Group, Inc., and Liberty Media Corp.*, 23 FCC Rcd 3265, ¶ 87 (2008); *Adelphia Order* ¶ 128.

[18] Press Release: ''ACA Applauds DOJ For Requiring Disney To Divest 22 Fox Regional Sports Networks'' (June 27, 2018), *available at* http://www.americancable.org/aca-applauds-doj-for-requiring-disney-to-divest-22-fox-regional-sports-networks/.

EXHIBIT 2
TO RESPONSE

From: Sukhbir Sadana
Sent: Thursday, August 16, 2018 11:01:24 AM (UTC-05:00) Eastern Time (US & Canada)
To: Delrahim, Makan (ATR); ATR-LitIII-Information; [redacted]
Subject:

Sukhbir Sadana,
Bangalore,
India.
Cell: [redacted]

Mr.Makan Delrahim,
Head-anti-trust dept.
Dept. of Justice
Washington DC.

Dear Mr.Delrahim,
The anti-trust department has green-lighted the Fox-Films and Disney merger for $ 71 billion in just 6 months time (one year before the scheduled time in 2019.)

In comparison, AT & T and Time Warner merger was in "consideration" for 18 months by the DOJ before the deal went through a few weeks back.

This is highly unusual.

There is also high probability that there was a “bid-rigging” method used for the merger by Disney to jack-up the price of the merger.

In this kind of fraud, two CEOs of competing companies and the CEO of the target company join hands in pushing up the merger price of the company artificially by bidding higher than their rival.

The spoils are later divided through seemingly “legitimate” transactions or money-laundering methods between the two / three CEOs and nobody is the wiser.

Just see how this happened :

Bob Iger bids $ 52 billion for Fox in December 2017 (with a reverse break-up fee clause of $ 2.5 billion which Disney would have to pay to Fox if it broke the deal.)

Then Comcast "bids" $ 65 billion for Fox (with no intention of buying because there is no reverse break-up fee clause.)

Then Bob Iger bids $ 71 billion in June 2018 and the Disney board "agrees".

There is an additional debt of $ 14 billion on Fox which takes the merger price to $ 85 billion.

Even if Disney doesn't pay a single cent as dividend to its share-holders for the next 10 years it will be very difficult for Disney to break even.

The share-holders meeting on June 27, 2018 in the New York Hilton lasted only 9 minutes when the head-of-legal of Disney Mr.Alan Braverman said - "99% of share-holders have voted by proxy and have approved the merger."

This was a ridiculous lie because in any kind of voting there are at least 20% people who have differing views.

Mr.Braverman refused to divulge names of share-holders who have voted "for" this merger which is a dead give-away of this rigged share-holders meeting.

Why was nobody from the anti-trust department there in this meeting to verify his claims ?!

Disney has also refused to reveal the names of Banks who have lent $ 14 billion to Fox and so there is a strong possibility that this money too will be swindled.

We are all wondering why you didn't point out these discrepancies to the Federal judge who has to approve this merger.

Nowhere on the DOJ's website is the name of the judge/court where this case is being heard.

Please do discuss the case with this hon'ble Attorney General of the DOJ - Mr.Jeff Sessions.

There are still 10 days left in this court for objections by the public.

I would appreciate it if you could reply to my email and give me the name of the relevant judge and court where I could file my objection.

regards,
Sukhbir

CC: Mr.Jeff Sessions (Attorney General-DOJ), Mr.Rod Rosenstein (Deputy-AG)

[FR Doc. 2019–08373 Filed 4–24–19; 8:45 am]
BILLING CODE 4410–11–C

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On April, 19, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Colorado in the lawsuit entitled *United States and State of Colorado* v. *HighPoint Operating Corporation,* Civil Action No. 1:19–cv–01151.

The lawsuit seeks injunctive relief and civil penalties for violations of the Clean Air Act, the Colorado Air Pollution Prevention and Control Act (''Colorado Act''), Colorado's federally approved State Implementation Plan (''Colorado SIP''), and Colorado Air Quality Control Commission Regulation Number 7 (''Regulation No. 7'') at tank batteries (referred to in the consent decree as ''Tank Systems'') that are, or were until recently, owned and operated by HighPoint Operating Corporation (''HighPoint'') in a portion of the Denver-Julesburg Basin in Colorado (known as the ''8-Hour Ozone Control Area'') designated as non-attainment with the National Ambient Air Quality Standards for ground-level ozone. The violations relate to alleged failures to adequately design, operate, and maintain vapor control systems at the Tank Systems, resulting in emissions of volatile organic compounds (''VOC'') and other pollutants to the atmosphere.

The proposed Consent Decree covers HighPoint's Tank Systems in the 8-Hour Ozone Control Area equipped with vapor control systems pursuant to Regulation No. 7 to achieve required system-wide emission reductions (50 tank batteries). Under the terms of the proposed Consent Decree HighPoint will ensure vapor control systems adequately capture and control potential VOC emissions from storage tanks by performing engineering evaluations of the vapor control systems and either making any necessary modifications to ensure adequate capture and control or installing an automated system that will monitor Tank System pressure and automatically control oil and gas flow rates into the Tank Systems and shut in equipment (including wells) to avoid excess emissions. HighPoint will also conduct monthly optical gas-imaging infrared camera (IR camera) inspections of all Tank Systems and implement a directed inspection and preventative maintenance program. The Decree will result in substantial reductions in VOC emissions from HighPoint Tank Systems throughout the ozone nonattainment area. The EPA and Colorado Department of Health and Environment (''CDPHE'') estimate the Decree's injunctive relief requirements to modify vapor control system design, improve operations and maintenance practices, and increase monitoring will reduce emissions from HighPoint's tank systems by approximately 350 tons per year (tpy). Additionally, HighPoint will complete a mitigation project it estimates will reduce emissions of VOC by approximately another 50 tpy.

HighPoint will pay a civil penalty of $330,000, of which $275,000 will go to the United States, and $55,000 to Colorado. Colorado and HighPoint have agreed that HighPoint will perform a state-only supplemental environmental project (to be designated) that will cost up to $220,000. Entering into and fully complying with the proposed Consent Decree will release HighPoint from past civil liability at the Tank Systems and associated vapor control systems for violations of the Colorado SIP and Regulation No. 7 relating to VOC emissions from condensate storage tanks.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Colorado* v. *HighPoint Operating Corporation,* D.J. Ref. No. 90–5–2–1–11484. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $34.75 (25 cents per page reproduction cost) payable to the United States Treasury for a copy of the Consent Decree without appendices. For a paper copy without the appendices, the cost is $21.25.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–08329 Filed 4–24–19; 8:45 am]

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DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request, Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study, New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data about the Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before June 24, 2019.

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

Email: ChiefEvaluationOffice@dol.gov; Mail or Courier: Megan Lizik, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW, Washington,

DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Megan Lizik by email at *ChiefEvaluationOffice@dol.gov* or by phone at (202) 430–1255.

SUPPLEMENTARY INFORMATION:

I. Background: DOL funds RESEA programs across all 50 states, DC, Puerto Rico, and the Virgin Islands. States and territories use these funds to address the reemployment services needs of Unemployment Insurance (UI) claimants and to prevent and detect UI improper payments (Unemployment Insurance Program Letter 8–18). The Bipartisan Budget Act of 2018 (Pub. L. 115–123) included amendments to the Social Security Act (SSA) that create a permanent authorization for the RESEA program. The permanently authorized RESEA program in Section 306 of the SSA provides for a phased implementation of new program requirements over several years, one of which is to ''establish and expand the use of evidence-based interventions'' in states' RESEA programs. To help meet this requirement and build evidence about RESEA, DOL is conducting an implementation study that will provide an understanding of current RESEA programs and program components being implemented in the field. As part of this implementation study, DOL will conduct a web-based survey of all RESEA grantees nationwide. This **Federal Register** Notice provides the opportunity to comment on a new proposed information collection activity that will be used for the implementation study.

• *Web-based survey instrument.* The evaluation team will conduct a survey of all states and territories operating RESEA programs to systematically gather up-to-date information about RESEA program operations not available in existing documents. This includes detail on how reemployment services are provided, interactions with federal workforce programs, how eligibility assessment and enforcement are carried out, types of reemployment services provided, and exploratory information about evaluation activities.

II. Desired Focus of Comments: Currently, the Department of Labor is soliciting comments concerning the above data collection for the Evaluation to Advance Reemployment Services and Eligibility Assessments Program Evidence. DOL is particularly interested in comments that do the following:

○ Evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;

○ evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions;

○ 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—for example, permitting electronic submissions of responses.

III. Current Actions: At this time, the Department of Labor is requesting clearance for for the survey protocol to be administered with all RESEA grantees nationwide.

Type of Review: New information collection request.

OMB Control Number: 1290–0NEW.

Affected Public: State RESEA program administrators.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument	Number of respondents [a]	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
Web-based survey instrument for State RESEA administrators	[b] 18	1	18	2	36
Total	18	1	18	2	36

[a] We are seeking a clearance period of three years.
[b] Assumes approximately 1 survey participant from each of approximately 53 state and territory RESEA programs over the three-year clearance period.

Christina Yancey,

Acting Chief Evaluation Officer, U.S. Department of Labor.

[FR Doc. 2019–08354 Filed 4–24–19; 8:45 am]

BILLING CODE 4510–HX–P

NATIONAL COUNCIL ON DISABILITY

Sunshine Act Meetings

TIME AND DATE: The Members of the National Council on Disability (NCD) will hold a quarterly hold business meeting and community forum on Friday, May 24, 2019, 9:00 a.m.–4:00 p.m., Atlantic Standard Time (Same as Eastern Daylight Time), in San Juan, Puerto Rico. Registration is not required.

PLACE: This meeting will occur at San Juan Marriott, located at 1309 Ashford Avenue, San Juan, Puerto Rico 00907–1324. Interested parties may join the meeting in person at the meeting location or may join by phone in a listening-only capacity (other than the period allotted for public comment noted below) using the following call-in information: Teleconference number: 1–866–556–2308; Conference ID: 8457105; Conference Title: NCD Meeting; Host Name: Neil Romano. In the event of teleconference disruption or failure, attendees can follow the meeting by accessing the Communication Access Realtime Translation (CART) link provided. CART is text-only translation that occurs real time during the meeting and is not an exact transcript.

MATTERS TO BE CONSIDERED: The Council will receive agency updates on policy projects, finance, governance, and other business. Following agency updates, the

Council will receive a presentation on highlights from NCD's upcoming report on involuntary institutionalization of people with disabilities during and after disasters; a panel with the Puerto Rico Disability Community Relief Network; a presentation on ''Rebuilding after a Disaster;'' a public comment session; and any unfinished business before adjourning.

Agenda: The times provided below are approximations for when each agenda item is anticipated to be discussed (all times Atlantic Standard Time):

Friday, May 24

9:00 a.m.–9:05 a.m. Welcome and Introductions From NCD Chairman Romano
9:05 a.m.–9:25 a.m. Welcome From Puerto Rico
9:25 a.m.–10:25 a.m. Executive Reports
10:25 a.m.–11:45 a.m. Highlights From NCD's Upcoming Report on Institutionalization During and After Disasters
11:45 a.m.–1:00 p.m. Break for Lunch
1:00 p.m.–2:00 p.m. Puerto Rico Disability Community Relief Network
2:00 p.m.–2:15 p.m. Break
2:15 p.m.–3:15 p.m. Rebuilding After a Disaster
3:15 p.m.–3:45 p.m. Public Comment—We Want to Hear From you!
3:45 p.m.–4:00 p.m. Unfinished Business
4:00 p.m. Adjourn

Public Comment: Your participation during the public comment period provides an opportunity for us to hear from you—individuals, businesses, providers, educators, parents and advocates. Your comments are important in bringing attention to the issues in your community. Priority will be given to in-person attendees. Each person will be given 3 minutes to present comment. If you are presenting as a group and prefer to choose a spokesperson, your group representative will be given 6 minutes to provide comment. To ensure your comments are accurately reflected and become part of the public record, NCD requests electronic submission prior to the meeting or immediately after to *PublicComment@ncd.gov*. Any individual interested in providing public comment is asked to register their intent to provide comment in advance by sending an email to *PublicComment@ncd.gov* with the subject line ''Public Comment'' with your name, organization, state, and topic of comment included in the body of your email. Full-length written public comments may also be sent to that email address. All emails to register for public comment at the quarterly meeting must be received by Wednesday, May 22, 2019.

CONTACT PERSON FOR MORE INFORMATION: Anne Sommers, NCD, 1331 F Street NW, Suite 850, Washington, DC 20004; 202–272–2004 (V), 202–272–2074 (TTY), or *asommers@ncd.gov*.

Accommodations: An assistive listening system, computer assisted real-time transcription, and sign language interpreters will be available. A CART streamtext link has been arranged for this meeting. The web link to access CART (in English) on Friday, May 24, 2019 is: *http://www.streamtext.net/player?event=NCD–QUARTERLY*. ASL and tri-lingual sign language interpreters will be present. If you require Spanish CART or additional accommodations, please send an email no later than Friday, May 3 to Ana Torres-Davis at *atorresdavis@ncd.gov,* indicating ''Accommodations'' in the subject line.

To help reduce exposure to fragrances for those with multiple chemical sensitivities, NCD requests that all those attending the meeting in person refrain from wearing scented personal care products such as perfumes, hairsprays, and deodorants. Flash photography and video documentation may occur during the meeting. Please alert staff if you are affected by photo sensitivity. Attendance at the meeting indicates consent to be photographed and recorded for NCD public affairs activities.

Due to last-minute confirmations or cancellations, NCD may substitute agenda items without advance public notice.

Dated: April 23, 2019.

Sharon M. Lisa Grubb,

Executive Director.

[FR Doc. 2019–08479 Filed 4–23–19; 4:15 pm]

BILLING CODE 8421–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–128 and CP2019–137; MC2019–129 and CP2019–138; MC2019–130 and CP2019–139; MC2019–131 and CP2019–140]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 29, 2019.

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
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s),

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–128 and CP2019–137; *Filing Title:* USPS Request to Add Priority Mail Contract 523 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Gregory Stanton; *Comments Due:* April 29, 2019.

2. *Docket No(s).:* MC2019–129 and CP2019–138; *Filing Title:* USPS Request to Add Priority Mail Contract 524 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Gregory Stanton; *Comments Due:* April 29, 2019.

3. *Docket No(s).:* MC2019–130 and CP2019–139; *Filing Title:* USPS Request to Add Priority Mail Contract 525 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* April 29, 2019.

4. *Docket No(s).:* MC2019–131 and CP2019–140; *Filing Title:* USPS Request to Add Parcel Return Service Contract 16 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* April 29, 2019.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2019–08343 Filed 4–24–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 19, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 525 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–130, CP2019–139.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08327 Filed 4–24–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 19, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 524 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–129, CP2019–138.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08326 Filed 4–24–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 19, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 523 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–128, CP2019–137.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08325 Filed 4–24–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Return Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* April 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 19, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Parcel Return Service Contract 16 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–131, CP2019–140.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–08328 Filed 4–24–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85697; File No. SR–NYSEArca–2019–27]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete NYSE Arca Rule 8.800–E Setting Forth the Requirements for the NYSE Arca ETP Incentive Program

April 19, 2019.

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 10, 2019, NYSE Arca, Inc. (''NYSE Arca'' 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 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 delete NYSE Arca Rule 8.800–E setting forth the requirements for the NYSE Arca ETP Incentive Program (the ''Incentive Program''), which expired on July 31, 2017, and a related outdated reference to the Incentive Program in the Exchange's Schedule of Fee and Charges. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 delete NYSE Arca Rule 8.800–E setting forth the requirements for the Incentive Program, which expired on July 31, 2017, and a related outdated reference to the Incentive Program in the Exchange's NYSE Arca Equities Schedule of Fee and Charges.

Proposed Rule Change

In June 2013, the Securities and Exchange Commission (the ''Commission'') approved the Incentive Program as a one-year pilot program for issuers of certain exchange-traded products (''ETPs'') listed on the Exchange.[4] The Incentive Program was designed to incentivize Market Makers [5] to take Lead Market Maker (''LMM'') [6] assignments in certain lower volume ETPs by offering an alternative fee structure for such LMMs that would be funded from the Exchange's general revenues. The Exchange also made related amendments to its fee schedule to set forth the requirements for the Incentive Program.[7] The pilot period was originally scheduled to expire on September 3, 2014. The Exchange subsequently filed to extend the program in 2014,[8] in 2015,[9] and again in 2016.[10] However, the pilot was not thereafter extended or made permanent and expired on July 31, 2017.

The Exchange proposes to delete NYSE Arca Rule 8.800–E in its entirety as obsolete. As noted above, the Incentive Program expired at the end of July 2017. The Exchange proposes a related change to the NYSE Arca Equities Schedule of Fee and Charges to delete a reference to the Incentive Program in the portion of the fee schedule setting forth LMM transaction fees and credits.[11]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and with Section 6(b)(1) of the Act,[13] in particular, in that in that [sic] it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposed rule change is a non-substantive change that eliminates obsolete material from the Exchange's rulebook. The Exchange believes that the proposed rule change would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Act by its members and persons associated with its members, because ensuring that the Exchange's rules and fee schedule are accurate and do not contain obsolete material would contribute to the orderly operation of the Exchange by adding clarity and transparency to such documents.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it is not designed to address any competitive issue or have any competitive impact, but rather serve to update the Exchange's rulebook to promote clarity and consistency, thereby alleviating possible market participant confusion.

[4] *See* Securities Exchange Act Release No. 69706 (June 6, 2013), 78 FR 35340 (June 12, 2013) (SR–NYSEArca–2013–34) (the ''Incentive Program Approval Order'').

[5] A Market Maker is an ETP Holder that acts as a Market Maker pursuant to NYSE Arca Rule 7–E. *See* NYSE Arca Rule 1.1(z). An ETP Holder is a sole proprietorship, partnership, corporation, limited liability company, or other organization in good standing that has been issued an ETP. *See* NYSE Arca Rule 1.1(o).

[6] A Lead Market Maker refers to registered Market Maker that is the exclusive Designated Market Maker in listings for which the Exchange is the primary listing market. *See* NYSE Arca Rule 1.1(w).

[7] *See* Incentive Program Approval Order, 78 FR at 35340.

[8] *See* Securities Exchange Act Release No. 72963 (September 3, 2014), 79 FR 53492 (September 9, 2014) (SR–NYSEArca–2014–99).

[9] *See* Securities Exchange Act Release No. 75846 (September 4, 2015), 80 FR 54646 (September 10, 2015) (SR–NYSEArca–2015–78).

[10] *See* Securities Exchange Act Release No. 78497 (August 8, 2016), 81 FR 53524 (August 12, 2016) (SR–NYSEArca–2016–110).

[11] The Exchange filed to remove other obsolete language related to the Incentive Program from the Schedule of Fee and Charges in 2018. *See* Securities Exchange Act Release No. 83032 (April 11, 2018), 83 FR 16909 (April 17, 2018) (SR–NYSEArca–2018–20).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(1).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15] 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow the Exchange to augment the accuracy of their rulebook by removing the expired Incentive Program and related references in its fee schedule. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[19]

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2019–27 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–NYSEArca–2019–27. 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–NYSEArca–2019–27 and should be submitted on or before May 16, 2019.

[20] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–08333 Filed 4–24–19; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85696; File No. SR–NYSEArca–2019–24]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule Regarding Certain Credits

April 19, 2019.

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 8, 2019, NYSE Arca, Inc. (''NYSE Arca'' 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 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 the NYSE Arca Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective April 8, 2019.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] On March 28, 2019, the Exchange filed to amend the Fee Schedule for effectiveness on April 1, 2019 (SR–NYSEArca–2019–19) and withdrew such filing on April 8, 2019.

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 purpose of this filing is to modify the Fee Schedule, effective April 8, 2019, to modify the criteria for achieving various credits.

The Exchange currently provides a number of incentives for OTP Holders and OTP Firms (collectively, ''OTPs'') designed to encourage OTPs to direct additional order flow to the Exchange to achieve more favorable pricing and higher credits. Among these incentives are enhanced posted liquidity credits based on achieving certain percentages of NYSE Arca Equity daily activity, also known as ''cross-asset pricing.'' Similarly, because the Exchange allows Market Makers (''MMs'') to aggregate their volume executed on NYSE Arca with affiliated or Appointed Order Flow Providers (''OFPs''), MMs may encourage an increased level of activity from these participants to qualify for various incentives. As a result, NYSE Arca becomes a more attractive venue for Customer (and Professional Customer) orders offering enhanced rebates.

Pursuant to the Customer Penny Pilot Posting Credit Tiers (the ''Penny Credit Tiers''), Customer and Professional Customer orders that post liquidity and are executed on the Exchange earn a base credit of $0.25 per contract, and may be eligible for increased credits based on the participant's activity. Currently, there are 7 Penny Credit Tiers, with increasing minimum volume thresholds (as well as increasing credits) associated with each tier.

The Exchange proposes to modify the minimum volume thresholds for Tier 5, but will not modify the $0.48 per contract credit associated with this Tier. Specifically, the Exchange proposes to modify Tier 5 to require that an OTP achieve at least 0.22% (decreased from 0.35%) of Total Customer Average Daily Volume (''TCADV'') from Customer Posted interest in all issues, plus Executed ADV of at least 0.90% (increased from 0.80%) of U.S. Equity Market Share Posted and Executed on NYSE Arca Equity Market.[5] This proposed change seeks to incent OTPs to achieve this Tier by increasing trading on the equities market (while making the Tier easier to achieve based on the lower minimum threshold for options trading activity).

The Exchange also offers a Customer Incentive Program (the ''Incentive Program''), which offers OTPs the ability to earn one additional credit by achieving one of the five alternative minimum thresholds. The Exchange proposes to modify one of the alternatives. Specifically, the Exchange proposes that an OTP must achieve Executed ADV of 0.90% (increased from 0.80%) of U.S. Equity Market Share Posted and Executed on NYSE Arca Equity Market to be eligible for the associated $0.03 per contract credit (which credit is not changing). This proposed change is designed to encourage increased trading on NYSE Arca Equity Market.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed modifications to the Penny Credit Tiers and the Incentive Program are reasonable, equitable, and not unfairly discriminatory because they are designed to encourage more participants to qualify for the various Tiers or Incentives, particularly those with a cross-asset pricing component. The Exchange believes these proposed changes should result in more order flow being directed to the Exchange, including from affiliated or Appointed OFPs. The proposed modification to Tier 5 should incent OTPs to increase trading on the equities market, while making it easier to meet the requisite volume threshold in options trading. The Exchange notes that OTPs are still eligible to qualify for Tier 5 under the existing alternative (*see supra* note 5) based on posted Customer volume and Market Maker Electronic volume. By continuing to provide such alternative methods to qualify for a Tier or an Incentive, the Exchange believes the opportunities to qualify for credits is increased, which benefits all participants through both increased Customer (and Professional Customer) volume and increased Market Maker activity. Further, encouraging Market Maker activity on, as well as encouraging OFPs to send higher volumes of Customer orders to, the Exchange would also contribute to the Exchange's depth of book as well as to the top of book liquidity.

To the extent that order flow that adds liquidity is increased by the proposal, market participants will increasingly compete for the opportunity to trade on the Exchange, including sending more orders to reach higher Tiers or achieve alternative Incentives. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to the investing public and, thus, would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market.

The Exchange also believes the proposed changes would be available to all similarly-situated market participants on an equal and non-discriminatory basis. The Exchange believes the proposed modifications are reasonable, equitable and not unfairly discriminatory because they encourage participants to enhance their order flow to qualify for the various incentives, including encouraging more participants to have affiliated or appointed order flow directed to the Exchange, which potential increase in order flow would benefit the investing public by improving order execution and price discovery, which promotes just and equitable principles of trade and removes impediments to, and perfects the mechanism of, a free and open market.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, 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. Instead, the Exchange believes that the proposed changes would encourage

[5] The Exchange is not modifying the alternative basis for an OTP to achieve Tier 5, which requires an OTP to achieve at least 0.75% of TCADV from Customer posted interest in all issues, plus at least 0.45% of TCADV from Market Maker Total Electronic Volume.

competition, including by attracting additional liquidity to the Exchange, which would continue to make the Exchange a more competitive venue for, among other things, order execution and price discovery. The Exchange does not believe that the proposed changes would impair the ability of any market participants or competing order execution venues to maintain their competitive standing in the financial markets. Further, the incentive would be available to all similarly-situated participants, and, as such, the proposed changes would not impose a disparate burden on competition either among or between classes of market participants and, in fact, may encourage competition.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[6] of the Act and subparagraph (f)(2) of Rule 19b–4[7] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–NYSEArca–2019–24 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–NYSEArca–2019–24. 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–NYSEArca–2019–24 and should be submitted on or before May 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–08332 Filed 4–24–19; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(2).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85695; File No. SR–BOX–2019–12]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 7130

April 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2019, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''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 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7130. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxoptions.com*.

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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

BOX Rule 7130(a)(4) governs the criteria for order matching and trade execution priority on BOX. BOX Rule 7130(a)(4)(iv), Options Participant Match Trade Prevention, describes an exception to the order matching and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

trade priority within that rule. Under this exception, a Participant may direct that its Market Maker or broker dealer orders entered on BOX not execute against Market Maker quotes or orders, or broker dealer orders that originated from such Participant and were resting on the BOX Book.

The Exchange now proposes to amend Rule 7130 to remove the Options Participant Match Trade Prevention rule discussed above and adopt three forms of Self-Trade Prevention modifiers. Specifically, the Exchange proposes the Cancel Newest, Cancel Oldest, and Cancel Both Self-Trade Prevention modifiers. Under this proposal, a BOX Participant may elect for all of its orders to be marked with a Self-Trade modifier.[3] If a Participant makes such an election, any order that is submitted will be prevented from executing against a resting opposite side order or quote that is labeled as originating from the Same Participant (for purposes of this rule, orders and quotes originating from the same Participant ID). A Participant may only elect one of the following: Cancel Newest, Cancel Oldest, or Cancel Both Self-Prevention options.

The Exchange also proposes IM–7130–2(c). This provision states that Participants who elect for Self-Trade Prevention modifiers may also elect for all of their resting interest to be ''skipped over.'' [4] In choosing to have their resting interest ''skipped over,'' incoming orders may trade with another eligible order or quote originating from any origin other than the Same Participant ID (for purposes of this rule, ''Another Participant ID''). If the Participant elects for resting interest to be ''skipped over,'' the incoming order may only trade with another eligible order or quote originating from Another Participant ID if the other (Another) Participant ID order or quote is at the price of the order or quote from the Same Participant ID that is being ''skipped over.'' The resting order or quote that was ''skipped over'' will remain on the BOX Book with the same priority. This election will apply to each of the modifiers discussed herein.

Below are examples of each Self-Trade Prevention modifier (some which include the election for resting interest to be ''skipped over''):

Cancel Newest

First, the Exchange proposes the STP Cancel Newest (''STPN'') modifier.[5] If a Participant chooses this modifier, any incoming order submitted by a Participant will not execute against opposite side interest from the Same Participant ID. The incoming order will be cancelled back to the Participant. The resting order or quote from the Same Participant will remain on the BOX Book.

STPN Example 1: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Newest Self-Trade Prevention modifier rests on the BOX Book with no resting interest behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming order to sell 10 contracts @ $1.00 is then cancelled back to the originating Participant. The resting buy order for 10 contracts $1.00 remains on the BOX Book.

STPN Example 2: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Newest Self-Trade Prevention modifier (and has elected for its resting orders to be ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $1.00 from Another Participant resting behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming sell order for 10 contracts @ $1.00 would not trade with the order to buy 10 contracts @ $1.00 from the Same Participant, but would trade with the order to buy 10 contracts @ $1.00 from the other Participant resting behind the buy order from the Same Participant because the price is at the Same Participant buy order.[6] The resting buy order for 10 contracts @ $1.00 from the Same Participant will remain on the BOX Book because the Participant elected for its resting orders to be ''skipped over.''

STPN Example 3: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Newest Self-Trade Prevention modifier (and has not elected for its resting orders to the ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $1.00 from Another Participant resting behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming sell order for 10 contracts @ $1.00 from the Same Participant is cancelled back to the Same Participant (because the Participant did not elect for its resting orders to be ''skipped over''). The resting sell order for 10 contracts @ $1.00 from the Same Participant will remain on the BOX Book.

STPN Example 4: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Newest Self-Trade Prevention modifier (and has elected for its resting interest to be ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $0.99 from Another Participant resting behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming sell order for 10 contracts would not trade with the order to buy 10 contracts @ $1.00 from the Same Participant and would also not trade with the order to buy 10 contracts @ $0.99 from Another Participant resting behind the buy order from the Same Participant.[7] The incoming sell order for 10 contracts is then cancelled back to the originating Participant. The resting buy order for 10 contracts @ $1.00 from the Same Participant remains on the BOX Book.

Cancel Oldest

Next, the Exchange proposes the STP Cancel Oldest (''STPO'') modifier. If a Participant chooses this modifier, any incoming order submitted by a Participant will not execute against opposite side resting interest from the same Participant ID. When a Participant submits an incoming order that would trade against opposite side resting interest from the same Participant ID, the opposite side interest will be cancelled back to the Participant.

STPO Example 1: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Oldest Self-Trade Prevention modifier rests on the BOX Book with no resting interest behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The resting buy order for 10 contracts @ $1.00 is then cancelled back to the originating Participant. The incoming sell order for 10 contracts @ $1.00 is entered into the BOX Book.[8]

[3] To elect for all orders to be marked with a Self-Trade Prevention modifier, Participants must contact the Market Operations Center (''MOC''). Such election will be effective until the Participant receives MOC's written confirmation of the Participant's written discretion to discontinue the effectiveness of the election for such Participant.

[4] Similar to the election for Self-Trade Prevention modifiers, Participants must contact the MOC if they elect for all of their resting interest to be ''skipped over.'' Such election will be effective until the Participant receives MOC's written confirmation of the Participant's written discretion to discontinue the effectiveness of the election for such Participant.

[5] The Exchange notes that the Cancel Newest modifier is similar to the functionality of the current Options Participant Match Trade Prevention.

[6] The Exchange notes that the incoming order would have been cancelled had the Participant not elected for its resting interest to be ''skipped over.''

[7] This is because the price of the eligible order from Another Participant ID is not at the same price level as the resting order on the BOX Book. As such, the incoming order is cancelled back to the Participant.

[8] In this example, regardless of whether the Participant elected for its resting interest to be

STPO Example 2: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Oldest Self-Trade Prevention modifier (and has elected for its resting interest to be ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $1.00 from Another Participant resting behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming sell order for 10 contracts @ $1.00 would trade with the order to buy 10 contracts @ $1.00 from the other (Another) Participant resting behind the buy order from the Same Participant. The resting buy order from the Same Participant will remain on the BOX Book.

STPO Example 3: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Oldest Self-Trade Prevention modifier (and has not elected for its resting interest to be ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $1.00 from Another Participant resting behind it. An order to sell 10 contracts at $1.00 comes in from the Same Participant. The resting buy order for 10 contracts @ $1.00 from the Same Participant is cancelled back to the Same Participant. The incoming sell order for 10 contracts @ $1.00 would trade with the order to buy 10 contracts @ $1.00 from the other (Another) Participant resting behind the buy order from the Same Participant.

STPO Example 4: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Oldest Self-Trade Prevention modifier rests on the BOX Book with another order to buy 10 contracts @ $0.99 from Another Participant resting behind it. An order to sell 10 contracts comes in from the Same Participant. The resting buy order for 10 contracts @ $1.00 is cancelled back to the originating Participant. The incoming sell order for 10 contracts would trade with the order to buy 10 contracts @ $0.99 from Another Participant that had been resting behind the buy order from the Same Participant (since the resting buy order from the Same Participant was cancelled).[9]

Cancel Both

Lastly, the Exchange proposes the STP Cancel Both (''STPC'') modifier. If a Participant chooses this modifier, any incoming order submitted by a Participant will not execute against opposite side resting interest from the same Participant ID. When a Participant submits an incoming order that would trade against opposite side resting interest from the same Participant ID, the entire size of both orders (or order and resting quote) will be cancelled back to the originating Participant ID.

STPC Example 1: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Both Self-Trade Prevention modifier rests on the BOX Book with no resting interest behind it. An order to sell 10 contracts @ 1.00 comes in from the Same Participant. Both orders would be cancelled back to the Participant.[10]

STPC Example 2: An order to buy 10 contracts @ $1.00 from a Participant who has elected for the Cancel Both Self-Trade Prevention modifier (and has elected for its resting interest to be ''skipped over'') rests on the BOX Book with another order to buy 10 contracts @ $1.00 from Another Participant resting behind it. An order to sell 10 contracts @ $1.00 comes in from the Same Participant. The incoming order would trade with the order to buy 10 contracts @ $1.00 from the other (Another) Participant resting behind the order from the Same Participant. The resting order will remain on the BOX Book.

As explained above, orders may skip over orders or quotes from the Same Participant ID and trade against eligible orders or quotes with lower priority that originate from Another Participant, provided the prices are the same. Therefore, the Exchange proposes to add IM–7130–2(d) to provide that in instances in which the Self-Trade Prevention modifiers are implicated, the Self-Trade Prevention modifier rules will supersede other allocation methods only for the purpose of preventing self-trades as described in the Self-Trade Prevention modifier rule. The Exchange notes that this rule is similar to another rule that was in place at another exchange.[11]

Additional Discussion

The Exchange notes that the proposed modifiers discussed herein are similar to modifiers used at other options exchanges.[12] The Exchange believes that the proposed changes will allow BOX Participants to better manage order flow and prevent undesirable or unexpected executions with themselves. Given enhancements in technology in today's trading environment, Participants often have multiple connections into the Exchange. Orders, for example, routed by the Same Participant via different connections may, in certain circumstances, trade against each other. The proposed STP modifiers would

''skipped over,'' the result would be the same because there is no resting interest behind the resting Participant order.

[9] In this example, the resting order will be cancelled back to the Participant regardless of whether the Participant has elected to allow for the resting order to be skipped because the buy order for 10 contracts @ $0.99 is at a different price behind the resting order.

[10] In this example, regardless of whether the Participant elected for its resting interest to be ''skipped over,'' the result would be the same.

[11] *See* Securities Exchange Act Release No. 67152 (June 7, 2012), 77 FR 35448 (June 13, 2012) (Order Approving SR–CBOE–2012–013). While this rule previously applied to Cboe's equities market, the Exchange believes that it should be permitted on the options market as it allows for increased executions without taking liquidity from the BOX Book which benefits all market participants.

[12] *See* Cboe BZX Exchange, Inc. (''Cboe BZX'') Rule 21.1(g). The Exchange notes a few minor differences between Cboe BZX's rule and BOX's proposed rule. First, the Exchange notes that it is not copying Cboe BZX Rule 21.1(g)(3) and (5). These rules detail two modifiers that BOX does not wish to offer on the Exchange at this time. Second, the Exchange notes that it is not copying certain language in Cboe BZX Rule 21.1(g) that states that the ''modifier on the incoming order controls the interaction between two orders marked with modifiers.'' Under the Proposal, if a Participant elects for its orders to be marked with one of the three proposed modifiers, all orders will be marked with the elected modifier, not on an order-by-order basis. Third, the Exchange notes that proposed IM–7130–2(c) differs from the Cboe BZX rule. As proposed, Participants who elect for Self-Trade Prevention modifiers may also elect for resting interest to be ''skipped over.'' Participants may elect for their resting interest to be ''skipped over'' so incoming orders may trade with another eligible order or quote originating from any origin other than the Same Participant ID (for purposes of this rule, ''Another Participant ID''). If the Participant elects for resting interest to be ''skipped over,'' the incoming order may only trade with another eligible order or quote originating from Another Participant ID if the other (Another) Participant ID order or quote is at the price of the order or quote from the Same Participant ID that is being ''skipped over.'' The resting order or quote that was ''skipped over'' will remain on the BOX Book. The Exchange notes that allowing Participants to elect whether its resting interest can be ''skipped over'' is reasonable and non-controversial as it will allow the incoming order to execute against the next resting order or quote on the BOX Book (as long as the next resting order or quote from Another Participant ID is at the price of the resting order or quote from the Same Participant that is being ''skipped over'') and allow the resting interest to remain on the BOX Book. The Exchange further notes that similar functionality was previously available at Cboe Exchange Inc (''Cboe'') for their Cancel Newest modifier. *See* Securities Exchange Act Release No. 67152 (June 7, 2012), 77 FR 35448 (June 13, 2012) (Order Approving SR–CBOE–2012–013). Further, the Exchange proposes to allow similar functionality discussed above in all proposed modifiers and not just the Cancel Newest modifier. Specifically, the Exchange proposes to allow Participants the ability to elect for their resting interest to be ''skipped over'' at the same price for both the STPO and STPC modifiers. The Exchange believes that this is reasonable and non-controversial as it will allow incoming orders to execute against the next resting order or quote on the BOX Book (as long as the next resting order or quote from Another Participant ID is at the price of the resting order or quote from the Same Participant ID) and allow the resting order from the Same Participant ID to remain on the BOX Book. As such, the Exchange believes that this functionality, while similar to the Cancel Newest modifier previously available at Cboe, should be applied to all of the proposed modifiers. The functionality will result in increased executions without taking liquidity from the BOX Book.

provide Participants the opportunity to prevent these potentially undesirable interactions occurring under the same Participant ID on both the buy and sell side of an execution.

As proposed, the STP modifiers would not be applicable to Qualified Contingent Cross (''QCC'') Orders, auctions (COPIP, Facilitation and Solicitation) and Qualified Open Outcry (''QOO'') Orders. Both QCC Orders and auctions are paired orders intended to serve a particular investment purpose that are contingent on the execution of the options legs, in the case of a QCC Order, and the execution of both sides of an auction order. Because the non-execution of a leg of a QCC Order or an auction order is contrary to the investment purpose of such orders, the Exchange has determined not to apply the STP modifiers in a manner that would prevent the execution of a QCC Order or an auction. Similarly, QOO Orders on the BOX Trading Floor are paired orders. The Exchange has determined not to apply the STP modifiers in a manner that would prevent the execution of such orders.

Implementation

The Exchange anticipates implementing the proposed change during the second quarter of 2019. The Exchange will provide notice of the exact implementation date, via Circular, prior to implementing the proposed change.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[13] in general, and Section 6(b)(5) of the Act,[14] in particular, that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change advances these objectives by making available to all Participants (not just Market Makers as the current rule provides) order modifiers that will assist them in preventing unwanted executions against themselves. Allowing all Participants to prevent unwanted executions against themselves removes impediments to and perfects the mechanism for a free and open market by allowing market participants to better manage order flow and prevent undesirable or unexpected executions with themselves. Further, the Exchange believes that expanding self-trade prevention to all Participants is reasonable and appropriate as similar functionality is available at other options exchanges in the industry.[15] Further, the Exchange notes that current rule 7130(a)(4)(iv) (Options Participant Match Trade Prevention) functions similar to the proposed Cancel Newest modifier. The Exchange believes that expanding self-trade prevention by adding Cancel Oldest and Cancel Both modifiers is reasonable as they exist at other options exchanges in the industry.[16] Further, as discussed herein, the Exchange believes that all proposed modifiers will allow Participants to better manage their order flow and prevent undesirable or unexpected executions with themselves.

The Exchange believes that proposed IM–7130–2(c) is reasonable as a similar rule was in place at another exchange.[17] As discussed above, the functionality that was previously available at Cboe was available on their equities market. The Exchange believes that the proposed functionality is appropriate and should be applied to the options market because it will allow increased executions on the Exchange without taking liquidity from the BOX Book, thus benefitting all market participants. Further, the Exchange notes that the proposed functionality was only available on Cboe's Cancel Newest STP modifier. The Exchange believes that expanding this functionality to all proposed modifiers is appropriate as it will allow increased executions, regardless of what modifier the Participant elects to use on its orders. For example, Participant A has elected for the Cancel Oldest Self-Trade Prevention modifier to be applied to all of their orders and has also elected for its resting interest to be ''skipped over.'' [18] Participant A has an order to buy 10 contracts @ $1.00 resting on the BOX Book with a Participant B buy order for 10 contracts $1.00 resting behind it. An order to sell 10 contracts @ $1.00 comes in from Participant A. Based on Participant A's elections, the incoming sell order for 10 contracts @ $1.00 would trade with Participant B's buy order for 10 contracts @ $1.00 and Participant A's resting buy order would remain on the BOX Book. Because Participant A elected for the skip over functionality, their resting buy order will be permitted to stay on the BOX Book despite their election of the STPO modifier. This election will, in turn, allow Participant A's resting interest the ability to stay on the BOX Book and potentially execute with another incoming sell order instead of being cancelled back to Participant A, thus potentially resulting in an execution that otherwise would not have occurred.

Further, the Exchange believes that adding proposed IM–7130–2(d) to provide that, in instances in which the Self-Trade Prevention modifiers are implicated, the Self-Trade Prevention modifier rules will supersede other allocation methods only for the purposes of preventing self-trades, as described in the proposed rule perfects the mechanism for a free and open national market system and protects investors and the public interest by removing any potential confusion regarding priority and allocation methods.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to enhance the Exchange's current Match Trade Prevention rule and will benefit Participants that wish to protect their orders and quotes against trading with other orders that originate from the same Participant ID. This new functionality, which is similar to functionality offered on other Exchanges, is also voluntary and the Exchange therefore does not believe that providing an enhanced offering to prevent against self-trading will have any significant impact on competition. The Exchange believes the proposed rule change is evidence of the competitive environment in the options industry where exchanges must continually improve their offerings to maintain competitive standing.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *See supra* note 12. *See also* Cboe EDGX Exchange, Inc. (''EDGX'') On EDGX, Match Trade Prevention (''MTP'') modifiers are available to all users, and not just Market Makers. The Exchange believes that expanding functionality to all Participants is appropriate as it will allow for all options market participants to better manage their order flow and prevent undesirable or unexpected executions with themselves.

[16] *See* Cboe BZX Exchange, Inc. (''Cboe BZX'') Rule 21.1(g). The Exchange again notes it is not proposing to include the modifiers codified in CboeBZX Rule 21.1(g)(3) and (5).

[17] *See* Securities Exchange Act Release No. 67152 (June 7, 2012), 77 FR 35448 (June 13, 2012) (Order Approving SR–CBOE–2012–013).

[18] The Exchange again notes that these voluntary functionalities (the STP modifiers and the ''skip over'' election) are applied to all orders by the Market Operations Center at the request of the BOX Participant.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20]

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–BOX–2019–12 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–BOX–2019–12. 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 such 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–BOX–2019–12 and should be submitted on or before May 16, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–08331 Filed 4–24–19; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. AB 6 (Sub-No. 498X)]

BNSF Railway Company—Abandonment Exemption—in Pawnee County, Okla.

BNSF Railway Company (BNSF) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon approximately 0.74 miles of Line Segment 1047 (formerly 7401), track 5403 between milepost 6.47 and milepost 7.21 in Pawnee County, Okla. (the Line). The Line traverses U.S. Postal Service Zip Code 74058.

BNSF has certified that: (1) No local traffic has moved over the Line since prior to 2008; (2) there is no overhead traffic on the Line; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication), 49 CFR 1152.50(d)(1) (notice to governmental agencies), and 49 CFR 1105.7 and 1105.8 (environment and historic report), have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) [1] has been received, this exemption will be effective on May 25, 2019, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues [2] must be filed by May 3, 2019. Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by May 6, 2019. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by May 15, 2019, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with Board should be sent to BNSF's representative, Peter Denton, Steptoe &

[1] The Board modified its OFA procedures effective July 29, 2017. Among other things, the OFA process now requires potential offerors, in their formal expression of intent, to make a preliminary financial responsibility showing based on a calculation using information contained in the carrier's filing and publicly available information. *See Offers of Financial Assistance,* EP 729 (STB served June 29, 2017); 82 FR 30,997 (July 5, 2017).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,800. *See* 49 CFR 1002.2(f)(25).

Johnson LLP, 1330 Connecticut Ave. NW, Washington, DC 20036.

If the verified notice contains false or misleading information, the exemption is void ab initio.

BNSF has filed a combined environmental and historic report that addresses the potential effects of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by April 30, 2019. The EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by BNSF's filing a notice of consummation by April 25, 2020, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov*.

Decided: April 22, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–08368 Filed 4–24–19; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1274X]

The Athens Line, LLC—Discontinuance of Service Exemption—in Oconee and Clarke Counties, Ga

The Athens Line, LLC (Athens Line), has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 13.8-mile rail line from milepost F–91.5 (at Bishop, Ga.) to milepost 105.3 (in Athens, Ga.) (the Line). The Line traverses U.S. Postal Service Zip Codes 30601, 30602, 30605, 30606, 30677, and 30621.

Athens Line has certified that: (1) No local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years; (3) no formal complaint filed by a user of rail service on the Line (or a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending before the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of the complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) [1] to subsidize continued rail service has been received, this exemption will be effective on May 25, 2019, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues must be filed by May 3, 2019, and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [2] must be filed by May 6, 2019.[3] Petitions for reconsideration must be filed by May 15, 2019, with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

A copy of any petition filed with Board should be sent to Athens Line's representative, Richard H. Streeter, Law Office of Richard H. Streeter, 5255 Partridge Lane NW, Washington, DC 20016.

[1] The Board modified its OFA procedures effective July 29, 2017. Among other things, the OFA process now requires potential offerors, in their formal expression of intent, to make a preliminary financial responsibility showing based on a calculation using information contained in the carrier's filing and publicly available information. *See Offers of Financial Assistance,* EP 729 (STB served June 29, 2017); 82 FR 30,997 (July 5, 2017).

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,800. *See* 49 CFR 1002.2(f)(25).

[3] Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov*.

Decided: April 19, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–08369 Filed 4–24–19; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36290]

Union Pacific Railroad Company—Trackage Rights Exemption—Norfolk Southern Railway Company

Union Pacific Railroad Company (UP) has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) to acquire trackage rights from Norfolk Southern Railway Company (NSR). UP states that NSR, pursuant to a written trackage rights agreement, has agreed to grant UP overhead trackage rights over approximately 288 miles of NSR's rail line between the UP/NSR connection at Control Point West MC at Birmingham, Mo., near milepost S266.3 and the UP/NSR connection at Control Point Iles at Springfield, Ill., near milepost DH 416.5.[1]

The verified notice states that the proposed transaction will provide UP with an alternative route between Kansas City, Mo., and Springfield, thereby increasing efficiency in operations.

The transaction may be consummated on or after May 9, 2019, the effective date of the exemption (30 days after the verified notice of exemption was filed).

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not

[1] A redacted version of the agreement between UP and NSR was filed with UP's verified notice of exemption. UP simultaneously filed a motion for a protective order to protect the confidential and commercially sensitive information in the unredacted version of the agreement, which UP submitted under seal. That motion will be addressed in a separate decision.

automatically stay the effectiveness of the exemption. Petitions for stay must be filed by May 2, 2019 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36290, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on UP's representative, Jeremy M. Berman, General Attorney, 1400 Douglas Street, Stop 1580, Omaha, NE 68179.

According to UP, this action is categorically excluded from environmental review under 49 CFR 1105.6(c), and from historic reporting under 49 CFR 1105.8(b)(3).

Board decisions and notices are available at *www.stb.gov*.

Decided: April 19, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–08370 Filed 4–24–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC).

DATES: The meeting will take place on May 30, 2019 from 9:00 a.m. to 5:00 p.m.

ADDRESSES: Department of Transportation (DOT) Headquarters, 1200 New Jersey Avenue SE, Washington, DC. Guests should allow time for security screening when entering the building.

FOR FURTHER INFORMATION CONTACT: Di Reimold, COMSTAC Executive Director; email *COMSTAC@faa.gov,* FAA Office of Commercial Space Transportation, 800 Independence Avenue SW, Room 331, Washington, DC 20591. Complete information regarding COMSTAC is available on the FAA website at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/*.

SUPPLEMENTARY INFORMATION:

The preliminary schedule for the COMSTAC meeting on May 30 is below:

—DOT Updates
—Industry Updates
—Infrastructure Working Group Discussion
—Safety Working Group Discussion
—Legal and Regulatory Working Group Discussion
—Competitiveness and Innovation Working Group Discussion
—Planning for future priorities

Attendance is open to the public but limited to the space available. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than May 18, 2019. Please provide the following information: Full legal name, country of citizenship, email address, and name of your industry association, or applicable affiliation. If you are attending as a public citizen, please indicate so.

For persons participating by telephone, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by email no later than May 18, 2019 for the teleconference call-in number and passcode. Callers are responsible for paying long-distance charges.

If you are in need of assistance or require a reasonable accommodation for this meeting, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section at least 10 calendar days before the meeting. Sign and oral interpretation can be made available if requested 10 calendar days before the meeting.

Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above and/or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact the person listed below in writing (mail or email) 10 DAYS IN ADVANCE OF MEETING so that the information can be made available to COMSTAC members for their review and consideration before the meeting. Written statements should be supplied in the following formats: One hard copy with original signature and/or one electronic copy via email. Portable Document Format (PDF) attachments are preferred for email submissions. A detailed agenda will be posted on the FAA website at *www.faa.gov/go/ast*.

Issued in Washington, DC, April 22, 2019.

Wayne Monteith,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2019–08365 Filed 4–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Waiver of Aeronautical Land-Use Assurances: New Century AirCenter Airport (IXD), New Century, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Intent of Waiver with respect to land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal from the Johnson County Airport Commission (sponsor), New Century, KS, to release 623.74+ acres of land from the federal obligation dedicating it to aeronautical use and to authorize this parcel to be used for revenue-producing, non-aeronautical purposes.

DATES: Comments must be received on or before May 28, 2019.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Aaron Otto, Executive Director, Johnson County Airport Commission, 1 New Century Parkway, New Century, KS 66031, (913) 715–6002.

FOR FURTHER INFORMATION CONTACT: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106, Telephone number (816) 329–2644, Fax number (816) 329–2611, email address: *lynn.martin@faa.gov*.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to change approximately 623.74+ acres of airport property at the New Century AirCenter Airport (IXD) from aeronautical use to non-aeronautical for revenue producing use. These parcels will be used for commercial/industrial operations.

No airport landside or airside facilities are presently located on these parcels, nor are airport developments

contemplated in the future. There is no current use of the surface of the parcels. These parcels will serve as revenue producing lots with the proposed change from aeronautical to non-aeronautical. The request submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the change to non-aeronautical status of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this Notice.

The following is a brief overview of the request:

The New Century AirCenter Airport (IXD) is proposing the release of five parcels, for a total of 623.74 acres, more or less from aeronautical to non-aeronautical. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The rental of the subject property will result in the land at the New Century AirCenter Airport (IXD) being changed from aeronautical to nonaeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market rental value for the property. The annual income from rent payments will generate a long-term, revenue-producing stream that will further the Sponsor's obligation under FAA Grant Assurance number 24, to make the New Century AirCenter Airport as financially self-sufficient as possible.

Following is a legal description of the subject airport property at the New Century AirCenter Airport (IXD):

Tract A

All that part of the Northeast Quarter of Section 7, Township 14 South, Range 23 East of the 6th Principle Meridian in Johnson County, Kansas, described as follows:

Commencing at the Southwest corner of the Northeast Quarter of said Section 7, thence North 88 degrees 01 minute 18 seconds East along the South line of the Northeast Quarter of said Section 7, a distance of 685.58 feet to the point of beginning; thence North 01 degree 55 minutes 50 seconds West, a distance of 2013.43 feet; thence North 87 degrees 53 minutes 18 seconds East, a distance of 494.00 feet; thence North 01 degree 55 minutes 50 seconds West, a distance of 564.26 feet to a point on the South right-of-way line of 151st street; thence Easterly along a curve to the right having an initial tangent bearing of North 89 degrees 47 minutes 42 seconds East, a radius of 11399.16 feet, a central angle of 0 degrees 47 minutes 58 seconds and an arc length of 159.05 feet; thence South 89 degrees 24 minutes 16 seconds East along the South right-of-way line of 151st street, a distance of 200.00 feet; thence Easterly along a curve to the left having a radius of 11519.16 feet, a central angle of 0 degrees 52 minutes 35 seconds and an arc length of 176.19 feet; thence South 0 degrees 38 minutes 01 seconds East along the West right-of-way line of New Century Parkway, now established, a distance of 455.68 feet; thence Southerly along a curve to the right having a radius of 1410 feet, a central angle of 6 degrees 27 minutes 44 seconds and an arc length of 159.03 feet, along said West right-of-way; thence Southerly along a curve to the right having a radius of 1279.30 feet an initial tangent bearing of South 07 degrees 05 minutes 55 seconds East, a central angle of 17 degrees 38 minutes 15 seconds and an arc length of 393.81 feet, along said West right-of-way line; thence along a curve to the right along said West right-of-way line, having a radius of 4479.10 feet, an initial tangent bearing of South 11 degrees 07 minutes 59 seconds West, a central angle of 03 degrees 30 minutes 19 seconds and an arc length of 273.81 feet; thence South 16 degrees 10 minutes 16 seconds West along said West right-of-way line, a distance of 272.86 feet; thence South 88 degrees 04 minutes 00 seconds West along said West right-of-way line, a distance of 94.51 feet; thence South 10 degrees 27 minutes 51 seconds East along said West right-of-way line, a distance of 200.38 feet; thence South 16 degrees 10 minutes 16 seconds West along said West right-of-way line, a distance of 873.28 feet to a point on the South line of the Northeast Quarter of said Section 7; thence South 88 degrees 01 minutes 18 seconds West along the South line of the Northeast Quarter of said Section 7, a distance of 490.09 feet to the point of beginning, containing 1,900,212.00 Sq. Ft. or 43.62 Ac. more or less, subject to that part in roads and easements.

Tract B

All that part of the Northeast Quarter of Section 7, Township 14 South, Range 23 East of the 6th Principle Meridian in Johnson County, Kansas, described as follows:

Commencing at the Northeast corner of the Northeast Quarter of said Section 7; thence South 01 degree 54 minutes 48 seconds East along the East line of the Northeast Quarter of said Section 7, a distance of 108.06 feet; thence South 88 degrees 05 minutes 12 seconds West, a distance of 20.00 feet to a point on the South right-of-way line of 151st Street also being the point of beginning; thence South 01 degree 54 minutes 48 seconds East parallel and 20 feet West of the East line of the Northeast Quarter of said Section 7, a distance of 1513.90 feet; thence South 88 degrees 04 minutes 00 seconds West, a distance of 1036.47 feet to a point of the East right-of-way line of New Century Parkway, now established, thence North 16 degrees 10 minutes 16 seconds East along said East right-of-way line, a distance of 247.77 feet; thence Northerly along a curve to the left having an initial tangent bearing of North 14 degrees 38 minutes 56 seconds East, a radius of 4559.10 feet, a central angle of 16 degrees 27 minutes 02 seconds and an arc length of 1309.00 feet to a point of the South right-of-way line of 151st Street; thence along a curve to the right having an initial tangent bearing of North 88 degrees 58 minutes 57 seconds East, a radius of 11519.16 feet, a central angle of 01 degree 05 minutes 35 seconds and an arc length of 219.76 feet; thence North 87 degrees 53 minutes 18 seconds East along the said South right-of-way line, a distance of 217.56 feet; thence South 83 degrees 34 minutes 45 seconds East along said South right-of-way line, a distance of 101.12 feet; thence North 87 degrees 53 minutes 18 seconds East along said South right-of-way line, a distance of 200.00 feet; thence North 83 degrees 39 minutes 33 seconds East along the South right-of-way line of 151st Street, a distance of 33.16 feet to the point of beginning, containing 1,305,862.08 Sq. Ft. or 29.97 Ac. more or less, subject to that part in roads and easements.

Tract C

All that part of the West half of Section 8, Township 14 South, Range 23 East of the 6th Principle Meridian in Johnson County, Kansas, described as follows:

Commencing at the Northeast corner of the Northwest Quarter of said Section 8; thence South 01 degree 50 minutes 43 seconds East along the East line of the Northwest Quarter of said Section 8, a distance of 95.00 feet to the point of beginning; thence continuing South 01 degree 50 minutes 43 seconds East along the said East line, a distance of 2550.52 feet to the Southeast corner of the Northwest Quarter of said Section 8; thence South 01 degree 51 minutes 09 seconds East along the East line of the Southwest Quarter of said Section 8, a distance of 664.19 feet; thence South 87 degrees 54 minutes 11 seconds West, a distance of 1394.30 feet; thence South 01 degrees 50 minutes 55 seconds East, a distance of 1951.05 feet to a point on the Northerly right-of-way line of 159th Street; thence South 87 degrees 54 minutes 29 seconds West along said Northerly right-of-way line, a distance of 189.54 feet; thence Northerly along a curve to the right having an initial tangent bearing of South 87 degrees 49 minutes 35 seconds West, a radius of 222.50 feet, a central angle of 90 degrees 15 minutes 47 seconds and an arc length of 350.52 feet to a point of the East right-of-way line of North Loop Road, as now established; thence North 01 degree 54 minutes 38 seconds West along said Easterly right-of-way line, a distance of 574.67 feet; thence North 01 degree 54 minutes 53 seconds West along said East right-of-way line, a distance of 1135.60 feet; thence Northerly along a curve to the left having initial tangent bearing of North 01 degree 35 minutes 50 seconds West, a radius of 611.09 feet, a central angle of 85 degrees 20 minutes 32 seconds and an arc length of 910.22 feet; thence North 06 degrees 35 minutes 50 seconds East, a distance of 68.55 feet to a point on the South line of the Northwest Quarter of said Section 8; thence continuing North 06 degrees 35 minutes 50 seconds East, a distance of 1037.49 feet; thence South 88 degrees 04 minutes 00 seconds West, a distance of 514.85 feet to a point on the West line of said Northwest Quarter, said point being 1027.04 feet North

of the Southwest corner of the Northwest Quarter of said Section 8; thence North 01 degree 54 minutes 48 seconds West along said West line, a distance of 1596.95 feet to a point on the South right-of-way line of 151st Street; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 20.06 feet; thence South 02 degrees 03 minutes 34 seconds East continuing along said South right-of-way line, a distance of 79.54 feet; thence North 83 degrees 39 minutes 58 seconds East along said South right-of-way line, a distance of 126.88 feet; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 200.00 feet; thence South 83 degrees 29 minutes 33 seconds East along said South right-of-way line, a distance of 202.24 feet; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 400.00 feet; thence North 82 degrees 15 minutes 58 seconds East along said South right-of-way line, a distance of 301.50 feet; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 900.00 feet; thence South 02 degrees 01 minutes 24 seconds East along said South right-of-way line, a distance of 20.00 feet; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 100.00 feet; thence North 85 degrees 06 minutes 51 seconds East along said South right-of-way line, a distance of 400.50 feet; thence North 87 degrees 58 minutes 36 seconds East along said South right-of-way line, a distance of 75.77 feet to the point of beginning, containing 8,586,565.91 Sq. Ft. or 197.12 Ac. more or less, subject to that part in roads and easements.

Tract D

All that part of Section 17, Township 14 South, Range 23 East of the 6th Principle Meridian in Johnson County, Kansas, described as follows:

Commencing at the Southeast corner of the Northeast Quarter of said Section 17; thence South 87 degrees 57 minutes 21 seconds West along the South line of the Northeast Quarter of said Section 17, a distance of 34.99 feet to the point of beginning; thence South 87 degrees 57 minutes 21 seconds West along the South line of the Northeast Quarter of said Section 17, a distance of 1324.62 feet to the Northeast corner of the West half of the Southeast Quarter of said Section 17; thence South 01 degree 41 minutes 01 second East along the East line of the West half of the Southeast Quarter of said Section 17, a distance of 2645.79 feet to the Southeast corner of the West half of the Southeast Quarter of said Section 17; thence South 88 degrees 03 minutes 28 seconds West along the South line of the Southeast Quarter of said Section 17, a distance of 1355.59 feet to the Southwest corner of the Southeast Quarter of said Section 17; thence South 88 degrees 03 minutes 36 seconds West along the South line of the Southwest Quarter of said Section 17, a distance of 2100.15 feet to a point 608.93 feet East of the Southwest corner of the Southwest Quarter of said Section 17; thence North 01 degree 41 minutes 15 seconds West, a distance of 1581.43 feet; thence North 45 degrees 03 minutes 45 seconds East, a distance of 2876.30 feet to a point on the West line of the Northeast Quarter of said Section 17; thence North 01 degree 45 minutes 46 seconds West along the said West line, a distance of 681.35 feet; thence North 45 degrees 08 minutes 14 seconds East, a distance of 1492.49 feet to a point on the South right-of-way line of 159th Street; thence North 87 degrees 40 minutes 07 seconds East along the South right-of-way line of 159th Street, a distance of 1278.56 feet; thence South 81 degrees 05 minutes 55 seconds East along the South right-of-way line of 159th Street, a distance of 255.11 feet to a point on the West right-of-way line of US 56 Highway; thence South 15 degrees 35 minutes 22 seconds East along said West right-of-way, a distance of 272.13 feet to a point 35 feet West of the East line of the Northeast Quarter of said Section 17; thence South 01 degree 46 minutes 14 seconds East along a line parallel to the East line of said Northeast Quarter, a distance of 2288.80 feet to the point of beginning, containing 15,369,040.89 Sq. Ft. or 352.82 Ac. more or less, subject to that part in roads and easements.

Tract E

All that part of the Southeast Quarter of Section 19, Township 14 South, Range 23 East 29.97 of the 6th Principle Meridian in Johnson County, Kansas, described as follows:

Commencing at the Southeast corner of the Southeast Quarter of said Section 19; thence South 88 degrees 00 minutes 41 seconds West along the South line of the Southeast Quarter of said Section 19, a distance of 367.09 feet; thence North 02 degrees 26 minutes 53 seconds West, a distance of 34.03 feet to the point of beginning thence North 01 degree 56 minutes 45 seconds West, a distance of 188.77 feet to a point on the South right-of-way line of US 56 highway; thence North 87 degrees 56 minutes 15 seconds East along the South right-of-way line of US 56 Highway, a distance of 60.00 feet; thence South 01 degree 56 minutes 45 seconds East, a distance of 178.30 feet to a point on the North right-of-way line of Santa Fe Street; thence South 78 degrees 02 minutes 42 seconds West along the North right-of-way line of Santa Fe Street, a distance of 60.93 feet to the point of beginning, containing 11,011.72 Sq. Ft. or 0.25 Ac. more or less, subject to that part in roads and easements.

Any person may inspect, by appointment, the request in person at the FAA office listed above **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the New Century AirCenter Airport.

Issued in Kansas City, MO on April 11, 2019.

Jim A. Johnson,

Director, Airports Division Central Region.

[FR Doc. 2019–08364 Filed 4–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0094]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Request for Comment; Fatality Analysis Reporting System

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on an extension of a previously-approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below will be forwarded to the Office of Management and Budget (OMB) for review, and requests comments on the ICR. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on February 1, 2019 (84 FR 1270). There were no comments received.

DATES: Comments must be submitted on or before May 28, 2019.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for NHTSA, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Barbara Rhea, State Data Reporting Systems Division (NSA–120), Room W53–304, 1200 New Jersey Avenue SE, Washington, DC 20590. Ms. Rhea can be reached via email at *barbara.rhea@dot.gov* or via phone at 202–366–2714. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). In compliance with these requirements, this notice announces that the following

information collection request has been forwarded to OMB.

A Federal Register notice with a 60-day comment period soliciting comments on the information collection was published on February 1, 2019 (84 FR 1270). There were no comments received.

Title: Fatality Analysis Reporting System.

OMB Control Number: 2127–0006.

Type of Request: Extension without change of a previously approved information collection.

Type of Review: Regular.

Affected Public: State Governments.

Abstract: Under both the Highway Safety Act of 1966 and the National Traffic and Motor Vehicle Safety Act of 1966, as amended, the National Highway Traffic Safety Administration (NHTSA) has the responsibility to collect accident data that support the establishment and enforcement of motor vehicle regulations and highway safety programs. These regulations and programs are developed to reduce the severity of injury and the property damage associated with motor vehicle accidents. The Fatality Analysis Reporting System (FARS) is a major system that acquires national fatality information directly from existing State files and documents. The total user population includes Federal and State agencies and the private sector.

The OMB approval for the survey is scheduled to expire on April 30, 2019. NHTSA seeks an extension of this approval to obtain this crash data vital to FARS' function.

Estimated Total Annual Burden Hours: 104,244 hours.

There are 52 State ''respondents'' reporting on approximately 34,748 fatal crash cases per year. The State employee (or employees depending on the number of fatal crashes per year occurring in the State) acquires and codes the required information as fatal crashes occur. Approximately 3.00 hours per case are necessary to complete the FARS forms. This results in an estimated annual burden of 104,244 hours.

Number of Respondents: 52.

FARS data is collected from the State governments from the 50 States, DC, and Puerto Rico.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.95.

Cem Hatipoglu,

Acting Associate Administrator for the National Center for Statistics and Analysis.

[FR Doc. 2019–08340 Filed 4–24–19; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Financial Recordkeeping and Reporting of Currency and Report of Foreign Bank and Financial Accounts

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before May 28, 2019 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov*.

SUPPLEMENTARY INFORMATION:

Financial Crimes Enforcement Network (FinCEN)

Title: Financial Recordkeeping and Reporting of Currency and Report of Foreign Bank and Financial Accounts.

OMB Control Number: 1506–0009.

Type of Review: Extension without change of a currently approved collection.

Description: The Bank Secrecy Act authorizes Treasury to require financial institutions and individuals to keep records and file reports that the Treasury determines have a high degree of usefulness in criminal, tax, or regulatory matters, or to protect against international terrorism. The information collected assist Federal, State, and local law enforcement in the identification, investigation, and prosecution of individuals involved in a variety of financial crimes.

Form: FinCEN 114.

Affected Public: Businesses or other for-profits, Individuals and Households.

Estimated Number of Respondents: 1,076,145.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 1,076,145.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 1,076,145.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 22, 2019.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2019–08358 Filed 4–24–19; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; ACH Vendor/Miscellaneous Payment Enrollment Form

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before May 28, 2019 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for

Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov*.

SUPPLEMENTARY INFORMATION:

Fiscal Service (FS)

Title: ACH Vendor/Miscellaneous Payment Enrollment Form.

OMB Control Number: 1530–0069.

Type of Review: Extension without change of a currently approved collection.

Description: Payment data is collected from vendors doing business with the Federal Government. The Treasury Department, Bureau of the Fiscal Service will use the information to electronically transmit payment to financial institutions designated by vendors and miscellaneous recipients.

Form: SF 3881.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 50,000.

Frequency of Response: Once, On Occasion.

Estimated Total Number of Annual Responses: 50,000.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 12,500.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 22, 2019.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2019–08357 Filed 4–24–19; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Veterans and Community Oversight and Engagement Board

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominations of qualified candidates to be considered for appointment as a member of the Veterans and Community Oversight and Engagement Board (herein-after referred in this section to as ''the Board'') for the VA West Los Angeles Campus in Los Angeles, CA (''Campus''). The Board is established to coordinate locally with the Department of Veterans Affairs to identify the goals of the community and Veteran partnership; provide advice and recommendations to the Secretary to improve services and outcomes for Veterans, members of the Armed Forces, and the families of such Veterans and members; and provide advice and recommendations on the implementation of the Draft Master Plan approved by the Secretary on January 28, 2016, and on the creation and implementation of any other successor master plans.

DATES: Nominations for membership on the Board must be received no later than 5:00 p.m. EST on June 15, 2019.

ADDRESSES: All nominations should be mailed to the Veterans Experience Office, Department of Veterans Affairs, 810 Vermont Avenue NW (30), Washington, DC 20420; or sent electronically to the Advisory Committee Management Office mailbox at *vaadvisorycmte@va.gov*.

FOR FURTHER INFORMATION CONTACT: Eugene W. Skinner Jr., Designated Federal Officer, Veterans Experience Office, Department of Veterans Affairs, 810 Vermont Avenue NW (30), Washington, DC 20420, telephone 202–631–7645 or via email at *Eugene.Skinner@va.gov*.

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth in the West LA Leasing Act, the Board shall: (1) Provide the community with opportunities to collaborate and communicate by conducting public forums; and (2) Focus on local issues regarding the Department that are identified by the community with respect to health care, implementation of the Master Plan, and any subsequent plans, benefits, and memorial services at the Campus. Information on the Master Plan can be found at *https://www.losangeles.va.gov/masterplan/*.

Authority: The Board is a statutory committee established as required by Section 2(i) of the West Los Angeles Leasing Act of 2016, Public Law 114–226 (the West LA Leasing Act). The Board operates in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

Membership Criteria and Qualifications: VA is seeking nominations for Board membership. The Board is composed of fifteen members and several ex-officio members. The Board meets up to four times annually; and it is important that Board members attend meetings to achieve a quorum so that Board can effectively carry out its duties.

The members of the Board are appointed by the Secretary of Veterans Affairs from the general public, from various sectors and organizations, and shall meet the following qualifications, as set forth in the West LA Leasing Act:

(1) Not less than 50% of members shall be Veterans; and

(2) Non-Veteran members shall be:

a. Family members of Veterans,

b. Veteran advocates,

c. Service providers,

d. Real estate professionals familiar with housing development projects, or

e. Stakeholders.

The Board members may also serve as Subcommittee members.

In accordance with the Board Charter, the Secretary shall determine the number, terms of service, and pay and allowances of Board members, except that a term of service of any such member may not exceed two years. The Secretary may reappoint any Board member for additional terms of service.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications including but not limited to subject matter experts in the areas described above. We ask that nominations include any relevant experience and information so that VA can ensure diverse Board membership.

Requirements for Nomination Submission: Nominations should be typed written (one nomination per nominator). Nomination package should include:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Board;

(2) The nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) The nominee's curriculum vitae, not to exceed three pages and a one-page cover letter; and

(4) A summary of the nominee's experience and qualifications relative to the membership criteria and professional qualifications criteria listed above.

The Department makes every effort to ensure that the membership of VA Federal advisory committees is diverse in terms of points of view represented and the committee's capabilities. Appointments to this Board shall be made without discrimination because of a person's race, color, religion, sex,

sexual orientation, gender identity, national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Board and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: April 22, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–08363 Filed 4–24–19; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 84 Thursday,
No. 80 April 25, 2019

Part II

Department of Health and Human Services

45 CFR Parts 146, 147, 148, et al.
Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 147, 148, 153, 155, and 156

[CMS–9926–F]

RIN 0938–AT37

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal Platform (SBE–FPs). It finalizes changes that will allow greater flexibility related to the duties and training requirements for the Navigator program and changes that will provide greater flexibility for direct enrollment entities, while strengthening program integrity oversight over those entities. It finalizes a change intended to reduce the costs of prescription drugs. This final rule also includes changes to Exchange standards related to eligibility and enrollment; exemptions; and other related topics.

DATES: These regulations are effective on June 24, 2019.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492–4305, Kiahana Brooks, (301) 492–5229, Ken Buerger, (410) 786–1190, or Abigail Walker, (410) 786–1725, for general information.

David Mlawsky, (410) 786–6851, for matters related to guaranteed renewability.

Avareena Cropper, (410) 786–3794, for matters related to sequestration.

Allison Yadsko, (410) 786–1740, for matters related to risk adjustment.

Jacalyn Boyce, (301) 492–5122, for matters related to Federally-facilitated Exchange and State-based Exchange on the Federal Platform user fees.

Abigail Walker, (410) 786–1725, Alper Ozinal, (301) 492–4178, Allison Yadsko, (410) 786–1740, or Adam Shaw, (410) 786–1091, for matters related to risk adjustment data validation.

Ken Buerger, (410) 786–1190, or LeAnn Brodhead, (410) 786–3943, for matters related to the opioid crisis.

Amir Al-Kourainy, (301) 492–5210, for matters related to Navigators.

Carly Rhyne, (301) 492–4188, for matters related to special enrollment periods.

Amanda Brander, (202) 690–7892, for matters related to exemptions.

Daniel Brown, (434) 995–5886, for matters related to direct enrollment.

Leigha Basini, (301) 492–4380, for matters related to health insurance issuer drug policy, essential health benefits, and qualified health plan certification requirements.

Abigail Walker, (410) 786–1725, for matters related to the required contribution percentage, cost-sharing parameters, and the premium adjustment percentage.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges'' are entities established under the Patient Protection and Affordable Care Act [1] (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage. Many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The PPACA also established the risk adjustment program.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. This rule will, within the limitations of the current statute, reduce fiscal and regulatory burdens across different program areas and provide stakeholders with greater flexibility.

Over time, issuer market exits and increasing insurance rates have threatened the stability of the individual and small group market Exchanges in many geographic areas. These dynamics have put coverage out of reach for many, notably those consumers enrolling outside of the Exchanges, who do not benefit from the PPACA's advance payments of the premium tax credit (APTC).

In previous rulemaking, we have established provisions and parameters to implement many PPACA requirements and programs. In this rule, we amend these provisions and parameters, with a focus on maintaining a stable regulatory environment to provide issuers with greater

[1] The PPACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs and providing states with additional flexibilities, reducing unnecessary regulatory burdens on stakeholders, empowering consumers, and improving affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off the Exchanges, and we are finalizing recalibrated parameters for the HHS-operated risk adjustment methodology. We are finalizing several changes related to the risk adjustment data validation program that are intended to ensure the integrity of the results of risk adjustment, and others intended to alleviate issuer burden associated with complying with risk adjustment data validation requirements.

As we do every year in the HHS notice of benefit and payment parameters, we are finalizing updated parameters applicable in the individual and small group markets. We are finalizing the user fee rate for issuers participating on Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal platform (SBE–FPs) for 2020 to be 3.0 and 2.5 percent of premiums, respectively. These rates are a decrease from past years, which will increase affordability for consumers. We are finalizing updates to the premium adjustment percentage methodology and amount, and consequently the maximum annual limitations on cost sharing for the 2020 benefit year, including those for cost-sharing reduction plan variations.

We are finalizing changes to the requirements regarding Navigators to reduce burden, increase flexibility, and enable Exchanges to more easily and cost-effectively operate Navigator programs. Streamlining the Navigator training requirements and authorizing but not requiring assisters to provide certain types of assistance, including post-enrollment assistance, will allow assisters to allocate their resources in a manner that best meets community needs, consumer demands, and organizational resources.

We are finalizing a number of changes in this rule that are intended to reduce the burden for consumers by making it easier to enroll in affordable coverage through the Exchanges. First, we are finalizing a policy that would provide additional flexibility to those in need of a hardship exemption that currently must be obtained by filing an application with an Exchange, by expanding the types of hardship exemptions that consumers may claim for 2018 through the tax filing process. Second, we believe consumers should have greater flexibility in how they shop for coverage, including the avenues through which they enroll in QHPs. As such, we have been working to expand opportunities for individuals to directly enroll in Exchange coverage through the websites of certain third parties, called direct enrollment entities, rather than having to visit *HealthCare.gov.* Third, we are finalizing several regulatory changes to streamline the regulatory requirements applicable to these direct enrollment entities. Fourth, we are finalizing a proposal to create a special enrollment period for off-Exchange enrollees who experience a decrease in household income and are determined to be eligible for APTC by the Exchange. This will allow enrollees to enroll in a more affordable on-Exchange product when a consumer's household income decreases mid-year.

We requested comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking applicable not sooner than plan year 2021.

In the proposed rule, we discussed why we believe increased transparency is a critical component of a consumer driven health care system, and expressed our interest to receive comments discussing ways to provide consumers with greater transparency with regards to their own health care data, QHP offerings on the FFEs, and the cost of health care services. We continue to believe that when consumers have access to relevant, meaningful, and consumer-friendly information, they are empowered to make more informed decisions with regards to their care.

The proposed rule discussed a future opportunity for public input on ways to increase the interoperability of patient-mediated health care data across health care programs, including in coverage purchased through the Exchanges. To that end, in the March 4, 2019 **Federal Register**, we published the ''Interoperability and Patient Access Proposed Rule'' with a 60-day public comment period. The Interoperability and Patient Access Proposed Rule includes policy proposals to make certain health care data easily accessible through common technologies in a convenient, timely, and portable way. We encourage public input on that proposed rule.

Additionally, we sought comment on ways to further implement section 1311(e)(3) of the PPACA, as implemented by 45 CFR 156.220(d), where a QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage for the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. We were particularly interested in input regarding what types of data will be most useful to improving consumers' abilities to make informed health care decisions, including decisions related to their coverage.

We also expressed our interest in ways to improve consumers' access to information about health care costs. We stated that we believe that consumers would benefit from a greater understanding of what their potential out-of-pocket costs would be for various services, based on which QHP they are enrolled in and which provider they see. We stated that we believe that such a policy would promote consumers' ability to shop for covered services, and to play a more active role in their health care.

We also are finalizing our proposal to create a limited data set file using masked enrollee-level data submitted to HHS from the External Data Gathering Environment (EDGE) servers for issuers of risk adjustment covered plans in the individual and small group (including merged) markets, with one modification: We will not make this limited data set available for public health or health care operations purposes. Thus, we are finalizing our proposal to make this file available to requestors who seek the data for research purposes only. In addition, we are finalizing our proposal to broaden the permissible HHS uses of the enrollee-level EDGE data currently submitted for purposes of risk adjustment. We believe this will increase understanding of these markets and contribute to greater transparency.

We sought comment on ways that we can promote the offering and take-up of high deductible health plans (HDHPs) that can be paired with health savings accounts (HSAs), which can serve as an effective and tax-advantageous method for certain consumers to manage their health care expenditures. We also sought comments for ways to increase the visibility of HSA-eligible HDHPs on *HealthCare.gov.*

In furtherance of the Administration's priority to reduce prescription drug costs and to align with the President's American Patients First blueprint, we proposed a series of changes regarding prescription drug benefits, to the extent permitted by applicable state law. These proposals included provisions that would allow issuers to adopt mid-year formulary changes to incentivize greater

enrollee use of lower-cost generic drugs and that would allow issuers to not count certain cost sharing toward the annual limitation on cost sharing if a consumer selects a brand drug when a medically appropriate generic drug is available. Based on issues raised by commenters, we are not finalizing these proposals. However, we are finalizing a change that would allow issuers and plans to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is available. We expect this change to support issuers' and plans' ability to lower the cost of coverage and generate cost savings while also ensuring efficient use of federal funds and sufficient coverage for people with diverse health needs.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets, including a guaranteed renewability requirement in the individual, small group, and large group markets.

Subtitles A and C of title I of the PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets.

Section 1302 of the PPACA provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, adherence to the cost-sharing limits described in section 1302(c) of the PPACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the PPACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1311(d)(3)(B) of the PPACA permits a state, at its option, to require QHPs to cover benefits in addition to the EHB. This section also requires a state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits.

Section 1302(d) of the PPACA describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the PPACA directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Sections 1312(f)(1) and (2) of the PPACA define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the PPACA, beginning in 2017, states have the option to allow issuers to offer QHPs in the large group market through an Exchange.[2]

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline to respond to requests for assistance.

Sections 1311(d)(4)(K) and 1311(i) of the PPACA direct all Exchanges to establish a Navigator program.

Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1312(c) of the PPACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the PPACA.

Section 1312(e) of the PPACA directs the Secretary to establish procedures under which a state may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for premium tax credits and cost-sharing reductions for QHPs sold through an Exchange.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA for, among other things, the establishment and operation of Exchanges.

Section 1311(c) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(e)(1) of the PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of individuals and employers in the state.

Sections 1313 and 1321 of the PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 establishes federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special

[2] If a state elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such state's large group market (except for self-insured group health plans) under section 2701(a)(5) of the PHS Act.

benefits derived from federal activities beyond those received by the general public.

Section 1321(d) of the PPACA provides that nothing in title I of the PPACA should be construed to preempt any state law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the PPACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the PPACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Internal Revenue Code (the Code), as added by section 1501(b) of the PPACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018.[3] Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals above the age of 30 qualify to enroll in catastrophic coverage under § 155.305(h).

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60, enacted on October 7, 2015) amended the definition of small employer in section 1304(b) of the PPACA and section 2791(e) of the PHS Act to mean, in connection with a group health plan for a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a state may treat as a small employer, for a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs [4]

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the 2015 fiscal year sequestration rates for the risk adjustment and reinsurance programs were announced.

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of the HHS risk adjustment models, and amendments to the risk adjustment data validation process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the risk adjustment data validation process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 benefit year risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional

[3] Public Law 115–97, 131 Stat. 2054 (2017).

[4] The term premium stabilization programs refers to the risk adjustment, risk corridors, and reinsurance programs established by the PPACA. See 42 U.S.C. 18061, 18062, and 18063.

recalibration related to an update to the 2016 enrollee-level EDGE dataset.[5]

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). This final rule sets forth additional explanation of the rationale supporting the use of the statewide average premium in the HHS-operated risk adjustment state payment transfer calculation for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.[6]

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

[5] ''Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[6] ''Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we released further guidance related to guaranteed availability.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and SHOP, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

We established additional standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In a final rule published in the March 27, 2012 **Federal Register** (77 FR 18309), we established the original regulatory Navigator duties and training requirements. In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42823), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant. This final rule also established a certified application counselor program for Exchanges and set standards for that program. In the 2017 Payment Notice final rule, published in the March 8, 2016 **Federal Register** (81 FR 12204), we expanded Navigator duties and training requirements. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we removed the requirements that each Exchange must have at least two Navigator entities; that one of these entities must be a community and consumer-focused nonprofit group; and that each Navigator entity must maintain a physical presence in the Exchange service area.

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin [7] that outlined our intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

6. Minimum Essential Coverage

In the February 1, 2013 **Federal Register** (78 FR 7348), we published a proposed rule that designates other health benefits coverage as MEC and outlines substantive and procedural requirements that other types of coverage must fulfill to be recognized as MEC. The provisions were finalized in the July 1, 2013 **Federal Register** (78 FR 39494).

In the November 26, 2014 **Federal Register** (79 FR 70674), we published a proposed rule seeking comments on whether state high risk pools should be permanently designated as MEC or whether the designation should be time-limited. In the February 27, 2015 **Federal Register** (80 FR 10750), we designated state high risk pools established on or before November 26, 2014 as MEC.

B. Stakeholder Consultation and Input

HHS consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP, and the risk adjustment and risk adjustment data validation programs. We held a number of listening sessions with consumers, providers, employers, health plans, and the actuarial community to gather public input. We solicited input from state representatives on numerous topics, particularly essential health benefits, QHP certification, Exchange establishment, and risk adjustment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 146, 147, 148, 153, 155, and 156.

The changes to 45 CFR parts 146, 147, and 148 make a non-substantive technical correction to the guaranteed renewability regulations.

The changes to the HHS risk adjustment program established under 45 CFR part 153 relate to the determination of the final coefficients for the 2020 benefit year, and the data sources used to calculate those coefficients. This final rule addresses high-cost risk pooling, where we finalize the same parameters that applied to the 2018 and 2019 benefit years to the 2020 benefit year and future benefit years unless changed in future rulemaking. The finalized provisions in part 153 also relate to the risk adjustment user fee for the 2020 benefit year and modifications to risk adjustment data validation requirements.

The final regulations in 45 CFR part 155 will provide more flexibility related to the training requirements for Navigators by streamlining 20 existing specific training topics into 4 broad categories. They also provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, but not required.[8] They amend and streamline our regulations related to direct enrollment. They also establish a new special enrollment period, at the option of the Exchange, for off-Exchange enrollees who experience a decrease in income and are newly determined to be eligible for APTC by the Exchange. They also increase flexibility for individuals seeking the general hardship exemption by allowing them to claim the exemption on their federal income tax return for 2018 without obtaining an exemption certificate number from the Exchange. Finally, they include several amendments to the definitions applicable to part 155.

The final regulations in 45 CFR part 156 set forth provisions related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2020. As we do every year in the HHS notice of benefit and payment parameters, we are finalizing updates to the premium adjustment percentage, which helps determine the required contribution percentage, the maximum annual limitation on cost sharing, and the reduced maximum annual limitation on cost sharing based on the premium adjustment percentage.

We finalize the FFE and SBE–FP user fee rates for 2020 to be 3.0 and 2.5 percent of premiums, respectively. The final regulations in part 156 also include a policy to incentivize the use of generic drugs. In addition, the final rule at part 156 includes changes related to direct enrollment to conform to the changes finalized to 45 CFR part 155.

III. Provisions of the Final Regulations and Analysis and Responses to Public Comments

In the January 24, 2019 **Federal Register** (84 FR 227), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' proposed rule (proposed 2020 Payment Notice or proposed rule). We received 26,129 comments, including 25,632 comments that were substantially similar to one of eight different letters. Comments were received from state entities, such as departments of insurance and state Exchanges; health insurance issuers; providers and provider groups; consumer groups; industry groups; national interest groups; and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that will not be addressed in this final rule.

In this final rule, we provide a summary of certain proposed provisions, a summary of the public comments received that directly related to those proposals, our responses to

[7] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[8] This assistance includes: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; understanding the availability of exemptions from the requirement to maintain MEC and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; the Exchange-related components of the premium tax credit reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

them, and a description of the provisions we are finalizing.

Comment: We received multiple comments criticizing the short comment period, stating that the length of the comment period made it difficult for stakeholders to conduct an in-depth analysis of the proposed rule. Commenters suggested that HHS adopt a comment period of at least 30 days from rule publication, and to fully comply with notice-and-comment requirements under the Administrative Procedure Act.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2020 plan year. A longer comment period would have delayed the publication of this final rule, and created significant challenges for states, Exchanges, issuers, and other entities in meeting deadlines related to implementing these rules. We continue to try to expand the comment period while also providing industry stakeholders with more time to implement the final rule.

Comment: We received multiple comments criticizing the timing of the release of the proposed rule, stating that publishing the proposal for this annual rule in January 2019 creates challenges for states, Exchanges, issuers, and other entities in implementing changes for plan year 2020.

Response: We recognize the importance of a timely release of updates to our regulations, and make every effort to do so efficiently. After the comment period closed, we took steps to expedite the publication of this final rule. We will continue to support consumers and stakeholders to implement the changes in this final rule in a timely fashion.

Comment: We received numerous comments cautioning us about making changes that would weaken the PPACA.

Response: Our top priority at HHS is putting patients first. While we have made great strides forward, there is still work to be done, including ensuring that coverage is affordable to all consumers. We have already made great strides in working to streamline our regulations and our operations with the goal of reducing unnecessary burden, increasing efficiencies and improving the patient experience. We will continue to seek innovative ways to reduce costs and burden while meeting the health needs of all Americans, within the constraints of the law. We are continuing to address feedback we receive from stakeholders and the public, and in turn we are making changes that will better serve patients and allow states to address the unique health needs of their populations.

We sought comment on ways to further implement section 1311(e)(3) of the PPACA, as implemented by § 156.220(d), to enhance enrollee cost-sharing transparency. We also sought comment on whether there are any existing regulatory barriers that stand in the way of privately led efforts at price transparency, and ways that we can facilitate or support increased private innovation in price transparency.

We requested comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking.

Comment: Commenters who addressed this topic unanimously supported retaining automatic re-enrollment processes. Supporters cited benefits such as the stabilization of the risk pool due to the retention of lower-risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, and lower premiums. Commenters stated that existing processes, such as eligibility redeterminations, electronic and document-based verification of eligibility information, periodic data matching, and premium tax credit reconciliations, are sufficient safeguards against potential eligibility errors and increased federal spending.

Response: We appreciate commenters' feedback and will take it into consideration as we continue to explore options to improve Exchange program integrity going forward. As we discussed in the preamble to the proposed rule, we agree that automatic re-enrollment significantly reduces issuer administrative expenses, makes enrolling in health insurance more convenient for consumers, and is consistent with broader industry practices. We are not making changes for these processes in this rule but will continue to consider the feedback provided for potential action in future rulemaking applicable not sooner than plan year 2021.

Comment: All commenters that commented on efforts to increase price transparency supported the idea of increased price transparency. Many commenters provided suggestions for how to disclose health care costs to consumers, such as providing costs for common, shoppable services, including costs for both in- and out-of-network health care, and accounting for consumer-specific benefit information such as progress towards meeting a deductible, out-of-pocket limit and visit limits in health care cost estimates. One commenter supported implementing price transparency requirements across all private markets. Another commenter suggested that price transparency efforts be a part of a larger payment reform, provider empowerment, and patient engagement strategy. Some commenters expressed caution for how such policies should be implemented, warning against duplicating state efforts and passing along administrative costs to consumers, and cautioning that the proprietary and competitive nature of payment data should be protected.

Response: We are not making changes to further implement the enrollee cost-sharing transparency requirements under § 156.220(d) as part of this rule. We will take this input into account as we continue our efforts to promote price transparency in health care markets.

We sought comment on ways that we can promote the offering and take-up of HDHPs that can be paired with HSAs. We also sought comments for ways to increase the visibility of HSA-eligible HDHPs on *HealthCare.gov*.

Comment: Many commenters provided suggestions on how to improve the educational content about HSAs on *HealthCare.gov*, and methods to improve the technical aspects of *HealthCare.gov* to incorporate HSAs into the QHP shopping experience. Commenters also encouraged HHS' involvement in the incorporation of value-based insurance design principles into HSA-eligible HDHP designs.

Response: We appreciate these comments, and will take them under consideration should we make any future changes to our approach towards HSAs on *HealthCare.gov*. We note that the rules for HSAs and HSA-eligible HDHPs are set forth in section 223 of the Code and are under the jurisdiction of the Department of the Treasury and the Internal Revenue Service (IRS).

A. Part 146—Requirements for the Group Health Insurance Market

For a discussion of the provisions in this final rule related to part 146, please see the preamble to part 147.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

Section 147.106 implements the guaranteed renewability requirements under the PPACA (applicable to non-grandfathered plans), and §§ 146.152 and 148.122 implement the guaranteed renewability requirements enacted by HIPAA (applicable to both grandfathered and non-grandfathered

plans). We proposed amendments in § 147.106, and conforming amendments to §§ 146.152 and 148.122, which, taken together with proposed amendments to §§ 156.122 and 156.130, aimed to reduce prescription drug expenditures.

In the 2016 Payment Notice, we expressed concerns about the impact on consumers of mid-year formulary changes. We noted that, under guaranteed renewability requirements and the definitions of ''product'' and ''plan,'' issuers generally may not make plan design changes, other than at the time of plan renewal. However, we also stated that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.[9]

In the proposed rule, we proposed to add § 147.106(e)(5) to set parameters in the individual, small group, and large group markets, for plan years beginning on or after January 1, 2020, for certain mid-year formulary changes, if permitted by applicable state law. At § 147.106(e)(5), we proposed allowing issuers, for plan years beginning on or after January 1, 2020, to make formulary changes during the plan year when a generic equivalent of a prescription drug becomes available on the market, within a reasonable time after that drug becomes available. We proposed that the issuer be permitted to modify its plans' formularies to add the generic equivalent drug. At that time, the issuer would also be permitted to remove the equivalent brand drug from the formulary or move the equivalent brand drug to a different cost-sharing tier on the formulary. We proposed that any mid-year formulary changes would have to be consistent with the standards applicable to uniform modifications in paragraph (e)(2) or (e)(3).

We proposed that issuers, including issuers of grandfathered plans, would also be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process under § 147.136 or the drug exception request process under § 156.122(c).

Under our proposal, before removing a brand drug from the formulary or moving it to a different cost-sharing tier, a health insurance issuer would be required to notify all plan enrollees of the change in writing a minimum of 60 days prior to initiating the change. This notice would identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan.

We also proposed changes to § 147.106(a) to reflect that paragraph (e) currently provides an exception to the general rule on guaranteed renewability. This is merely a technical correction, not a substantive change. We similarly proposed technical corrections to §§ 146.152(a) and 148.122(b).

We sought comment on these proposals related to prescription drug benefits and coverage, including whether to limit the proposal related to mid-year formulary changes to the individual and small group markets, and whether a different advance notice period, such as 90 days or 120 days, would be more appropriate.

Comment: While some commenters generally supported the proposal, many commenters opposed it, because they noted it inappropriately expanded or narrowed issuers' ability to make drug formulary changes mid-year. Several commenters opposed the proposal as overly restrictive. These commenters stated that federal law does not prohibit mid-year formulary changes, and that it is a current practice that occurs much more broadly than what the proposal would permit. For example, these commenters stated that formularies are changed when a biosimilar drug, a lower-priced brand name therapeutic equivalent, a new drug that is clinically effective, or an over-the-counter version of a drug becomes available; when there is a shortage of a preferred generic drug; when there is new evidence of the efficacy of a drug; or when there are expanded indications for a drug. One commenter stated that most states do not prohibit mid-year formulary changes, regardless of the federal guaranteed renewability requirements and stated that mid-year formulary changes should be allowed for all drugs as long as the changes are approved by the issuer's pharmacy and therapeutics committee, and notice is provided. Several commenters stated that approval by a pharmacy and therapeutics committee, notice to enrollees, and providing an exceptions process to request and gain access to removed drugs when medically appropriate and necessary, are all current industry practice.

Many other commenters stated the proposal would improperly allow mid-year formulary changes and opposed the proposal because they noted it would hurt consumers. These commenters stated, for example, that consumers choose their plans based on the formulary composition at the beginning of the plan year and that changing formularies could result in patient safety and health issues such as additional emergency room visits, additional outpatient appointments, and higher medical costs. A few commenters stated that these dangers could occur notwithstanding the availability of an exceptions or appeals process. Many commenters stated that mid-year formulary changes arbitrarily eliminate an EHB.

Response: In the 2016 Payment Notice, we stated that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate. Comments to this rule supported that belief. At the same time, in the 2016 Payment Notice, we also expressed concerns about the impact on consumers of mid-year formulary changes.[10] We appreciate the comments to this rule identifying potential negative impacts on consumers. Given the complexity of this issue, and the challenges of balancing the interests of consumers with the importance of mitigating the effects of rising prescription drug costs, we are not finalizing the proposal at this time. Rather, we will continue to examine the issue of mid-year formulary changes, and may provide guidance on this issue in the future. In the meantime, to the extent issuers make mid-year formulary changes consistent with applicable state law, our expectation is that all issuers (in the individual, small group and large group markets) will continue to provide certain consumer protections that, as commenters have stated, are generally consistent with current industry practice. These protections include pre-approval by a pharmacy and therapeutics committee, and reasonable advance notice to affected individuals of the mid-year removal of any drug from a formulary (or the placement of any drug on a higher cost-sharing tier). Additionally, we expect that affected individuals will generally have access to the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), under which enrollees and dependents may request and gain access to a non-formulary drug when clinically appropriate and not otherwise covered by the health plan.

[9] 80 FR at 10822.

[10] 80 FR 10822.

Several commenters specifically noted that issuers currently offer an exceptions process when making mid-year formulary changes. Therefore, our expectation is that issuers will also offer an appeals process or exceptions process when making mid-year formulary changes.

We do not agree that mid-year formulary changes arbitrarily eliminate an EHB. Rather, we remind issuers that all requirements in § 156.122 related to EHB as applied to prescription drug coverage continue to apply in the context of mid-year formulary changes. For example, a health plan does not provide EHB unless it covers the greater of one drug in every United States Pharmacopeia (USP) category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan. Additionally, the EHB regulations at § 156.122(a)(3) require the use of a pharmacy and therapeutics committee to establish and manage the formulary drug list throughout the year. Issuers required to provide EHB must continue to meet these requirements.

Comment: Many commenters, including those who generally support and those who generally oppose the proposal, requested specific changes to the proposal. One commenter favored applying mid-year formulary restrictions to issuers in the large group market, while a few opposed doing so. One commenter stated that the uniform-modification-of-coverage requirements should not apply to mid-year formulary changes in the large group market, while another stated they should not apply in any market. One commenter raised what it believed to be practical concerns with any restrictions on mid-year formulary changes in the group markets, since plan years in those markets are not required to align with the calendar year. Many commenters stated that mid-year formulary changes should be permitted as a way to add drugs, but not to remove drugs or move drugs to a different tier. A few commenters stated the formulary changes should not apply, for the rest of the plan year, to people already taking the affected drugs. Several commenters noted that we did not define ''generic drug,'' and offered definitions.

Response: As stated in this rule, we are not finalizing the proposal at this time, and instead intend to continue to examine the issue of mid-year formulary changes. We appreciate the important considerations raised by commenters, in particular regarding the practical concerns with restrictions on mid-year formulary changes, and believe it is important for us to more fully explore these issues and other issues raised by commenters prior to issuing further guidance. We will consider all of these comments as we consider future guidance in this area.

We also are not finalizing any changes to the definitions of ''plan'' and ''product'' at § 144.103—which incorporate by reference the uniform modification standards—with regard to determining whether a product and plan that have undergone formulary changes are considered the same product and plan. This definition provides that, among other things, within a product, each plan must have the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal level of coverage. We interpret this provision to mean that for modifications of prescription drug formularies, each tier must continue to have the same cost-sharing structure, or any changes to the tier structure must be related to changes in cost or utilization of medical care, or to maintain the same metal level, to be considered a uniform modification of coverage, regardless of any changes made to the placement of drugs within the formulary. Additionally, the product must provide the same covered benefits, except for any changes in benefits that cumulatively impact the plan-adjusted index rate for any plan within the product within an allowable variation of ±2 percentage points (not including changes pursuant to applicable federal or state requirements). Given the nature of formulary changes, our expectation is that generally, any changes to which drugs are covered under the formulary would not be of a magnitude that would exceed the allowable variation of ±2 percentage points of the plan-adjusted index rate. However, if formulary changes do result in a change to the plan-adjusted index rate outside this permitted variation, such changes would result in the product being considered to have been discontinued, and a new product to have been issued.

Comment: While many commenters generally supported the requirement for issuers to provide an appeals or exceptions process, a few commenters recommended requiring an exceptions process of all issuers, suggesting it is more protective than the appeals process. We did not receive any comments that generally opposed such a requirement. In describing current industry practice, multiple commenters pointed out that issuers making mid-year formulary changes already regularly provide affected consumers with access to the exceptions process.

Response: We agree with commenters that access to an appeals or exceptions process when a mid-year formulary change occurs is an important consumer protection. Although we are not finalizing our proposal, we note that issuers offering non-grandfathered group or individual health insurance coverage are required to provide an appeals or exceptions process under which enrollees and dependents may request and gain access to a non-covered drug, including one that was removed from the formulary (other than one removed for safety reasons) when clinically appropriate and not otherwise covered by the health plan, under §§ 147.136 or 156.122(c), as applicable. We expect issuers to continue to do so, with respect to mid-year formulary changes.

Comment: For the proposed notice requirement, many commenters generally agreed that a notice requirement is necessary, while only one stated otherwise. Many commenters agreed with the proposed 60-day advance notice requirement, while many advocated for a 90-day or 120-day requirement. A few commenters stated it should be 30 days, consistent with the notice Medicare requires under some circumstances. Many commenters stated that the notice should be sent only to affected enrollees, while others stated the notice should also be sent to prescribers and pharmacies. A few commenters requested either a template or specific language. A few commenters stated that a two-step notice should be provided: The first notice should apprise enrollees of the availability of the generic drug, as well as any cost advantage to switching; at least 90 days later, the issuer must provide a second notice, stating that changes to the brand drug's cost sharing will occur; and only 60 days after the second notice is sent, could the issuer change the brand drug's cost sharing. A few commenters stated that state law should determine the timing and content of notices. Several commenters stated that notice to enrollees is common industry practice when mid-year formulary changes occur.

Response: We agree with the many commenters who stated that providing advance notice to affected consumers is important, and although we are not finalizing the proposal at this time, we expect issuers will continue to provide reasonable notice to affected consumers, pending any further guidance on mid-year formulary changes. We will continue to examine this issue.

We received no comments on the proposed technical corrections to

§§ 146.152, 147.106, and 148.122, and are finalizing them as proposed.

C. Part 148—Requirements for the Individual Health Insurance Market

For a discussion of the provisions in this final rule related to part 148, please see the preamble to part 147.

D. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2019,[11] both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2019 sequestration. The federal government's 2019 fiscal year began October 1, 2018. Although the 2016 benefit year was the final year of the transitional reinsurance program, we continue to make reinsurance payments in the 2019 fiscal year for close-out activities. Therefore, the risk adjustment and reinsurance programs will be sequestered at a rate of 6.2 percent for payments made from fiscal year 2019 resources (that is, funds collected during the 2019 fiscal year).

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99–177, enacted on December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment programs, the funds that are sequestered in fiscal year 2019 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2020 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs will be sequestered in future fiscal years, and any sequestered funding will become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges. In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. HHS did not receive any requests from states to operate risk adjustment for the 2020 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2020 benefit year.

a. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2019 Payment Notice.[12] The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a cost-sharing reduction adjustment that accounts for differences in induced demand at various levels of cost sharing.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score or PLRS) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

i. Definitions (§ 153.20)

In this final rule, we are making a technical correction to the definition of a risk adjustment covered plan under § 153.20 by correcting a citation in the definition of ''risk adjustment covered plan'' from § 146.145(c) to § 146.145(b). Specifically, this definition was finalized in the final rule entitled Standards Related to Reinsurance, Risk Corridors and Risk Adjustment,[13] and after that rule was finalized, the final rule entitled Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 [14] amended and redesignated the numbering under § 146.145. Among other things, these amendments moved the excepted benefit provision from paragraph (c) to paragraph (b) of § 146.145. Thus, the purpose of this technical correction is to update this citation to refer to the paragraph on excepted benefit plans under § 146.145, consistent with the original intent of this definition when it was first adopted.

ii. Updates to the Risk Adjustment Model Recalibration

We used the 3 most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. For the 2019 benefit year, we recalibrated the models using 2 years of MarketScan® data (2014 and 2015) and 2016 enrollee-level EDGE data. The 2019 benefit year was the first recalibration year in which enrollee-level EDGE data was used for this purpose. This approach used blended (averaged) coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available. For the 2020 benefit year, we proposed to blend the 2 most recent years of enrollee-level EDGE data available (2016 and 2017) with the most recent year of MarketScan® data available (2017). We also noted that if we are unable to publish the final coefficients in the final rule, consistent with § 153.320(b)(1)(i), and as we have done for certain prior benefit years,[15] we would publish the final coefficients for the 2020 benefit year in guidance after the publication of the final rule. We sought comments on these proposals.

[11] ''OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2019'', p. 6. February 12, 2018. Available at *https://www.whitehouse.gov/wp-content/uploads/2018/02/Sequestration_Report_February_2018.pdf.*

[12] See 83 FR 16930 at 16939.

[13] 77 FR 17220 (March 23, 2012).

[14] 78 FR 65046 (October 30, 2013).

[15] For example, see 2018 Payment Notice final rule, 81 FR 94058 (December 22, 2016). Also see *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Final-HHS-RA-Model-Coefficients.pdf.*

We did not propose to make any changes to the categories included in the HHS risk adjustment models for the 2020 benefit year from those finalized in the 2019 benefit year models. That is, we proposed to maintain the same age, sex, enrollment duration, HCC, RXC, and severity categories for the 2020 benefit year models as those used for the 2019 benefit year models.[16] However, we proposed to make a pricing adjustment for one RXC coefficient for the 2020 benefit year adult models. Consistent with our treatment of other RXCs where we constrain the RXC coefficient to the average cost of the drugs in the category,[17] we proposed to make a pricing adjustment to the Hepatitis C RXC to mitigate overprescribing incentives in the 2020 benefit year adult models. For the RXC coefficients listed in Table 1 of the proposed rule, we constrained the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. This had the material effect of reducing the Hepatitis C RXC and the RXC–HCC interaction coefficients. For the final 2020 benefit year Hepatitis C factors in the adult models, we proposed to adjust the plan liability associated with Hepatitis C drugs to reflect future market pricing of Hepatitis C drugs before solving for the adult models' coefficients. We proposed applying an adjustment to the plan liability to ensure that plans can continue to receive incremental credit for enrollees having both the RXC and HCC for Hepatitis C, and allow for differential plan liability across metal levels. We sought comment on these proposals.

We are not finalizing our proposal to blend the most recent year of MarketScan® data (2017) with the 2 most recent years of enrollee-level EDGE data (2016 and 2017) for 2020 risk adjustment model recalibration. We are instead finalizing an approach that would blend 3 consecutive years of data—one year of data from MarketScan® (2015) with the 2 most recent years of enrollee-level EDGE data (2016 and 2017), an approach that more closely aligns with the approach we used to recalibrate risk adjustment models for the 2016, 2017, 2018, and 2019 benefit years. This approach maintains our previously finalized policy of blending coefficients from 3 years of separately solved models and promotes stability for the risk adjustment coefficients year-to-year. Accordingly, we have incorporated the 2015 MarketScan® data with 2016 and 2017 benefit year enrollee-level EDGE data for the final 2020 benefit year risk adjustment coefficients presented in this final rule. Additionally, we are finalizing the pricing adjustment to the plan liability simulation for the Hepatitis C RXC, as proposed, and are not otherwise making changes to the categories included in the HHS risk adjustment models for the 2020 benefit year from those finalized for the 2019 benefit year models.

The following is a summary of the public comments we received on the risk adjustment model recalibration proposals.

Comment: Most commenters supported using enrollee-level EDGE data to recalibrate the risk adjustment models, with some commenters especially supporting the blending of 2016 and 2017 enrollee-level EDGE data and 2017 MarketScan® data for the recalibration of the 2020 risk adjustment models. Some commenters stated that they had expected the 2020 benefit year models to incorporate coefficients solved from the 2015 MarketScan® data to maintain 2 of the same data years (2015 MarketScan and 2016 enrollee-level EDGE) as those used in the 2019 benefit year models. These commenters raised concerns that using 2017 MarketScan® and 2017 enrollee-level EDGE data may result in double counting certain enrollees to the extent the individual and small group market plans contribute data to MarketScan®, and suggested that using currently available 2015 MarketScan® data with 2016–2017 enrollee-level EDGE data to recalibrate the 2020 risk adjustment models would allow the final coefficients to be published with the final rule. One of these commenters was concerned about volatility in coefficients relative to prior years, which blended 3 consecutive years of data (rather than 2 data sets from the same year), wanting more information on whether this volatility would be reduced if 2015 MarketScan® data were used. Some commenters supported HHS' intent to propose use of 3 consecutive years of enrollee-level EDGE data to recalibrate the risk adjustments models for the 2021 benefit year and beyond. One commenter supported maintaining the categories included in the HHS risk adjustment models for the 2020 benefit year.

Response: We believe blending multiple years of data promotes stability and certainty for issuers in rate setting, helping to smooth significant differences in coefficients solved from any one year's dataset, particularly for conditions with small sample sizes. Because the MarketScan® data generally represent enrollees in the large self-insured employer market and the enrollee-level EDGE data represents enrollees in the small group and individual markets, using two datasets from the same year (2017 MarketScan® and 2017 enrollee-level EDGE) would not significantly double count enrollees between the different datasets for the 2017 benefit year. However, we agree with commenters who noted that maintaining 2 years of data from one recalibration year to the next has a stabilizing effect by spreading the impact of new experience over 3 years. We recognize and agree with the concerns that recalibrating the 2020 benefit year risk adjustment models blending 2017 MarketScan® data with 2016 and 2017 enrollee-level EDGE data may create unintentional volatility, as it would only maintain one of the three datasets that were used in the 2019 benefit year recalibration. Based on comments received, we are finalizing the 2020 benefit year risk adjustment models using blended coefficients from 2015 MarketScan® data, and 2016 and 2017 enrollee-level EDGE data. We intend to continue our efforts to recalibrate the risk adjustment models using enrollee-level EDGE data from issuers' individual and small group or merged market populations, and transition away from the MarketScan® commercial database. Specifically, beginning with the 2021 benefit year, we intend to propose to use the 3 most recent years of enrollee-level EDGE data available to recalibrate the risk adjustment models.

Comment: Several commenters requested that HHS provide the final coefficients in the final rule and the actual proposed coefficients to be proposed in proposed rules in future years. However, one commenter requested that the final coefficients be made available by March 31, 2019 due to state filing deadlines.

Response: We appreciate the commenter's concern that the final coefficients be made available by the time of initial state rate filing submissions. Our ability to provide the proposed and final coefficients in the proposed and final rules depends on the availability of data and our ability to execute the model regressions with that data to solve the coefficients for the risk adjustment models for a given benefit year, reflecting any applicable

[16] See 83 FR 16939.

[17] See Section 4.0, ''Constraints on RXC Coefficients to Limit Incentives for Inappropriate Prescribing'' of the Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memo. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

modifications adopted as part of the rulemaking process.

Due to the availability of data and our ability to execute the model regressions, this year, we are able to provide the final recalibrated coefficients for 2020 benefit year in the tables below. In the future, we will continue to look for opportunities to update our processes to obtain and process the recalibrated coefficients as soon as practical. However, if data is not available or if we are unable to calculate the coefficients for the risk adjustment models for a benefit year in time for publication in the applicable final annual HHS notice of benefit and payment parameters, then we will publish the draft factors to be employed in the models in the final rule, including demographic factors, diagnostic factors, and utilization factors, and the datasets to be used to calculate the final coefficients.[18] In such circumstances, we will also notify issuers in the final rule of the date by which final coefficients will be released in guidance.[19]

Comment: One commenter encouraged HHS to monitor the volatility of coefficients year-to-year in switching to enrollee-level EDGE data. One commenter recommended evaluating the models continually to ensure they fully capture the cost of the current standard of care for conditions. One commenter recommended HHS continue to contemplate the best way to incorporate drug pipeline data, while a different commenter supported continuing to reevaluate drugs. Another commenter supported monitoring and evaluating the impact on patient access of changes to the risk adjustment program.

Response: As with every recalibration year, we continue to monitor the year-to-year changes in risk scores, including the volatility of the coefficients from year to year. As discussed in the proposed rule, we noted that for HCCs with corresponding RXCs and RXC–HCC interaction factors in the adult risk adjustment models, we are observing year-to-year fluctuations in the risk score weights between the HCC, RXC, and RXC–HCC interaction factors. This fluctuation is mainly due to the collinearity between these factors, making the statistical models, and therefore, the coefficients solved for these factors, sensitive to small changes in the data. Although the HCC, RXC, and RXC–HCC interaction factors may be changing from year to year, the aggregate impact of the factors has remained relatively stable between recalibration updates. Similarly, the aggregate impact of the HCC, RXC and RXC–HCC interaction factors for the 2020 benefit year continues to be relatively stable.

Additionally, we have been continuously assessing the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment model. As a results of this on-going assessment, we make quarterly updates to the RXC Crosswalk [20] to ensure drugs, including new drugs, are being mapped to RXCs where appropriate, and intend to continue to make these updates in the future.

Overall, we also continue to regularly evaluate the individual and small group markets (including merged markets) and assess whether updates to the HHS-operated risk adjustment program could improve the assessment of plan actuarial risk. We also regularly review the impact of the risk adjustment program on the markets. We expect to continue to review the risk adjustment program and propose changes as necessary.

Comment: Most commenters generally supported a pricing adjustment for the Hepatitis C RXC coefficient to reflect changing drug prices. A few commenters were concerned that the proposal is over-adjusting the Hepatitis C RXC coefficient, and wanted clarification on the approach used for the adjustment. One commenter stated that HHS should modify the Hepatitis C RXC adjustment based on a days' supply variable. While some commenters agreed with the adjustment to Hepatitis C RXC to mitigate against the potential for misaligned incentives such as overprescribing, others disagreed with the implication that health plans influence providers' prescribing patterns.

Response: We found significant pricing changes due to the introduction of new Hepatitis C drugs into the market upon review of the Hepatitis C treatments that are approved and expected to be available before the 2020 benefit year.[21] Due to the lag between the data years used to recalibrate the risk adjustment models and the applicable benefit year, the data used for recalibrating the models do not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question. In addition, the first few years of enrollee-level EDGE data do not include days' supply information for the RXCs; thus, the enrollee-level EDGE datasets could not be used to model a variable for the days' supply of the Hepatitis C RXC. Since we are finalizing the risk adjustment models for the 2020 benefit year coefficients with the 2015 MarketScan® data, which represents even older and costlier Hepatitis C trends than what is anticipated in the 2020 benefit year, we continue to believe the pricing adjustment as proposed is appropriate.

We believe the pricing adjustment, as finalized, is appropriate based on our review of published expectations for plan liability associated with Hepatitis C drugs. Additionally, we agree with commenters that due to the high cost of these drugs, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2020 benefit year and could be incentivized to ''game'' risk adjustment or encourage overprescribing practices. We appreciate the commenters' view that plans generally do not influence prescribing patterns. However, to avoid perverse incentives to influence overprescribing behavior, we are finalizing the pricing adjustment as proposed. This pricing adjustment leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2020 benefit year plan liability associated with Hepatitis C drugs.

As such, we are finalizing our proposed pricing adjustment to make a pricing adjustment to more closely reflect the expected average additional plan liability of the Hepatitis C RXC for the 2020 benefit year. In making this determination, we consulted our clinical experts to assess whether the lower cost Hepatitis C drugs are substitutable to ensure that plans that cover various treatments would continue to be compensated for their incremental plan liability. We found that due to the generic entrant, prices for all variations of Hepatitis C drugs are expected to be significantly lower in the 2020 benefit year than those observed in the currently available datasets (which reflect prior benefit years). We believe this approach to estimating the Hepatitis

[18] See § 153.320(b)(1)(i).

[19] Ibid.

[20] April 4, 2019, was our last update of the 2018 Benefit Year Risk Adjustment (RA): Updated HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software—Technical Details that includes the RXC Crosswalk. The RXC Crosswalk is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-DIY-Tables-2018.xlsx.*

[21] See *https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic.* Also see *https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevir pibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.*

C plan liability appropriately balances reflecting the changes in costs of the Hepatitis C drugs in the market in the 2020 benefit year while limiting the potential for overprescribing incentives. We intend to reassess this pricing adjustment in future benefit years' model recalibrations with additional years of enrollee-level EDGE data.

Comment: Several commenters wanted HHS to consider incorporating the Pre-Exposure Prophylactics (PrEP) into the risk adjustment models, given the recent draft United States Preventive Services Task Force (USPSTF) Grade A recommendation [22] for clinicians to offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition, citing that the high cost for PrEP therapy is likely to lead to cost avoidance strategies by issuers. One commenter expressed support for including preventive services in the risk adjustment models.

Response: We appreciate the commenters noting the draft USPSTF recommendation, which, if finalized, would require issuers to cover a high cost-therapy with no cost sharing. However, we are not incorporating PrEP into the risk adjustment models. As a general principle, RXCs are incorporated into the HHS risk adjustment models to impute a missing diagnosis or indicate severity of a diagnosis. While preventive services are incorporated in the simulation of plan liability, they do not directly affect specific diagnoses. We incorporate preventive services into our models to ensure that 100 percent of those services are reflected in the plan's liability; however, many preventive services only count as preventive services under certain conditions. In the case of PrEP and the draft USPSTF recommendation, the recommendation is only applied if the enrollee meets certain conditions for ''persons who are at high risk.'' Some of the at-risk categories are not recorded in claims data, making them impossible to identify. Furthermore, the USPSTF recommendation for PrEP is only a draft recommendation, and we do not know if or when it would become final. We also note that we are aware of other current drugs that are preventive in nature that may be similar to PrEP in that they are medications recommended for a subset population that is at risk. While we do not plan to make an adjustment for PrEP at this time, we may consider soliciting comments in the future on whether and how to incorporate preventive medications into the risk adjustment models, and how to identify at-risk populations in the enrollee-level EDGE data that may be eligible for drugs classified as preventive services.

Comment: Some commenters noted concern about the enrollment duration factors in the adult models, and wanted HHS to consider further adjustments to these factors. For example, certain commenters discussed the differences between special enrollment period enrollees versus open enrollment period enrollees that drop coverage during the plan year. These commenters noted concerns that the current combined enrollee duration factors do not adequately address both scenarios, and wanted the enrollment duration factors to vary for these different scenarios. In particular, one of these commenters expressed concerns about the changes in the enrollment duration factors over time, stating that the factors never seemed to correctly adjust for increased special enrollment period spending (particularly for those with the maternity HCC), and provided several recommendations on potential modifications to improve the enrollment duration factors, including special consideration for maternity and NICU-related HCCs. Another commenter requested that HHS take a holistic look at the child risk scores and whether duration factors would be appropriate for incorporation into the child models, as well as the relationship of duration factors with risk scores to age rating factors. One commenter supported HHS making adjustments to give greater weight to the enrollee-level EDGE data when recalibrating the model coefficients if HHS finds significant demographic or distributional differences in the enrollee-level EDGE data compared to the MarketScan® data, and was supportive of HHS continuing to analyze the enrollee-level EDGE data to study key differences between the individual and small group markets, including costs, utilization patterns, induced demand, and partial year enrollment.

Response: While there are differences in total spending in MarketScan® data compared to enrollee-level EDGE data, we have found that the relative risk differences for age-sex, HCC, and RXC categories in the enrollee-level EDGE data are generally similar to those in the MarketScan® data. Therefore, we do not believe giving greater weight to the enrollee-level EDGE data is needed. Since the 2016 Risk Adjustment White Paper and Conference,[23] we have continued to assess options to update the enrollment duration factors in the risk adjustment adult models as we stated we would. With the 2017 enrollee-level EDGE data, we are now able to analyze whether to modify enrollment duration factors with a lens of differences between individual and small group markets, since the market identifier was not part of the 2016 enrollee-level EDGE data. Our preliminary analysis of 2017 enrollee-level EDGE data found that separate enrollment duration factors for the individual and small group markets in the adult models may be warranted, given the differences in risk profiles of partial year enrollees between the two markets. Small group market partial year enrollees had a lower incremental risk on average than the individual market partial year enrollees in the 2017 benefit year data. Additionally, we did not observe a significant additional risk for special enrollment period enrollees or enrollees who dropped coverage prior to the end of the benefit year in either market.

We did not propose and are not making any change to the current enrollment duration factors used in the adult risk adjustment models at this time. Our goal is to continue to analyze enrollee-level EDGE data; we will consider proposing changes to how partial year enrollees are accounted for in the risk adjustment models for future benefit years in notice-and-comment rulemaking. We intend to solicit feedback and recommendations in the future for potential updates to how partial year enrollees are accounted for in the risk adjustment models, including adjustments to the enrollment duration factors and the use of separate enrollment duration factors for individual and small group markets and may consider whether such factors should be incorporated in the child models.

iii. High-Cost Risk Pooling (§ 153.320) and Accounting for the High-Cost Risk Pool in the Risk Adjustment Transfer Methodology

HHS finalized a high-cost risk pool adjustment in the 2018 Payment Notice to account for the incorporation of risk associated with high-cost enrollees in the HHS risk adjustment models.[24] Specifically, we finalized adjusting the models for high-cost enrollees in risk

[22] U.S. Preventive Services Task Force, ''Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis'' (2018) available at *https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.*

[23] *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf* and *https://www.regtap.info/uploads/library/RA_ConferenceSlides_033116_5CR_040516.pdf.*

[24] 81 FR 94058 at 94080 (December 22, 2016).

adjustment covered plans beginning with the 2018 benefit year by excluding a percentage of costs above a certain threshold in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk, since the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees. In addition, to account for issuers' risk associated with high-cost enrollees, issuers of risk adjustment covered plans will receive a percentage of costs (coinsurance rate) above the threshold. We set the threshold and coinsurance rate at levels that will continue to incentivize issuers to control costs while improving the predictiveness of the HHS risk adjustment models. Issuers of risk adjustment covered plans with high-cost enrollees will receive a payment for the percentage of costs above the threshold in their respective transfers for the applicable benefit year. Using claims data submitted to the EDGE servers by issuers of risk adjustment covered plans, we calculate the total amount of paid claims costs for high-cost enrollees based on the threshold and the coinsurance rate. We then calculate a charge as a percentage of the issuers' total premiums in the individual (including catastrophic and non-catastrophic plans and merged market plans) or small group markets, which is applied to the total transfer amount in each market, thus maintaining the balance of payments and charges within the HHS-operated risk adjustment program. We finalized a threshold of $1 million and a coinsurance rate of 60 percent across all states for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets for the 2018 and 2019 benefit years.[25] For the 2020 benefit year and beyond, we proposed to maintain the same parameters that apply to the 2018 and 2019 benefit years, unless amended through notice and comment rulemaking.

Additionally, beginning with the 2018 benefit year, we added to the HHS risk adjustment methodology additional transfer terms to reflect the payments and charges assessed for the high-cost risk pool. To account for costs associated with exceptionally high-risk enrollees, we added transfer terms (a payment term and a charge term) that are calculated separately from the state payment transfer formula in the HHS-operated risk adjustment transfer methodology. Beginning for the 2018 benefit year, we finalized the addition of a term that reflects 60 percent of costs above $1 million ($HRP_i$), and another term that reflects a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payments and charges within the HHS-operated risk adjustment program for a given benefit year. We described in detail in the 2019 Payment Notice how these terms will be calculated in conjunction with the calculations under the state payment transfer formula for the 2019 benefit year.[26] These terms are described in detail in this rule, along with the calculations under the total state payment transfer formula, and are also highlighted as part of the illustration of the total risk adjustment transfer methodology below.

Similar to the 2019 benefit year, consistent with the proposed adoption of the same high-cost risk pool parameters (that is, a $1 million threshold and 60 percent coinsurance rate), we proposed to add a term that would reflect 60 percent of costs above $1 million ($HRP_i$) in the total plan transfer calculation and another term that would reflect a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payment and charges within the HHS-operated risk adjustment program for a given benefit year. We proposed to use a percentage of premium adjustment factor that would be applied to each plan's total premium amount, rather than the percentage of PMPM premium adjustment factor, consistent with the approach finalized in the 2019 Payment Notice. The percentage of premium adjustment factor applied to a plan's total premium amount would result in the same adjustment as a percentage of the PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. We proposed to apply these same terms for future benefit years that maintain the same underlying parameters for the high-cost risk pool adjustment (that is, $1 million threshold and 60 percent coinsurance rate).

We are finalizing the high-cost risk pool parameters and the additional terms to account for the high-cost risk pool in the risk adjustment transfer methodology as proposed for the 2020 benefit year and for future benefit years unless changed in notice-and-comment rulemaking. The following is a summary of the public comments we received on our proposal on the high-cost risk pool parameters and how to account for the high-cost risk pool in the risk adjustment transfer methodology.

Comment: Most commenters supported maintaining the high-cost risk pool parameters at the $1 million threshold and 60 percent coinsurance rate. One commenter disagreed with the high-cost risk pool methodology due to concerns that issuers may try to ''game'' the system by inflating the cost of high cost services to push payments over the threshold, and stated that the methodology creates another level of uncertainty that insurers will need to factor into their premiums. This commenter stated that if HHS wants to continue the reinsurance program, it should be pursued outside of risk adjustment, and suggested HHS should instead create a permanent reinsurance program, using Medicare pricing to reprice all claims over $1 million and account for geographic pricing variations in its calculation of the high-cost risk pool payment and charge terms. One commenter cautioned against drastically changing the parameters from year to year which could result in instability, and supported the national funding approach for this aspect of the HHS risk adjustment program, as it maintains a balance between the level of assessments applied to support the program and the allowance for some risk-pooling across states or geographic areas. One commenter noted the importance for states to consider the high-cost risk pool program when designing state-based reinsurance programs, and that section 1332 waiver applications should address the potential overlap between the section 1332 program and the federal risk adjustment program to minimize the likelihood of federal taxpayers compensating issuers twice for the same high value claims. One commenter recommended HHS solicit feedback on possible changes in a separate rulemaking to incorporate a high-cost risk pool stratification methodology, to consider adoption of multiple high-cost pool thresholds with increased coinsurance amounts, and to adjust the issuer charge calculation methodology to avoid penalizing lower-cost issuers. Another commenter requested the ability to comment on the high-cost risk pool parameters each benefit year. Some commenters requested that data on the specific transfer amounts attributable to the high-cost risk pool adjustment, with charges and claims reimbursed reported separately, be sent to issuers in the EDGE reports, and that HHS publish the net amount (reimbursed claims—charges) by state and issuer in the

[25] See 81 FR 94058 at 94080 and 83 FR 16930 at 16943.

[26] See 83 FR 16930 at 16954.

annual summary risk adjustment report with one requesting high-cost risk pool information in the interim risk adjustment report.

Response: We are finalizing the high-cost risk pool parameters and the approach for accounting for the high-cost risk pool payment and charge terms in the risk adjustment payment transfer methodology as proposed. As detailed in the 2018 Payment Notice,[27] we incorporated a high-cost risk pool calculation into the HHS risk adjustment methodology to mitigate any residual incentive for risk selection to avoid high-cost enrollees, and to ensure that, consistent with the statute, transfers better reflect the average actuarial risk of risk adjustment covered plans. It is not intended to be a continuation of the transitional reinsurance program established under section 1341 of the PPACA that ended at the conclusion of the 2016 benefit year. We continue to believe a $1 million threshold and 60 percent coinsurance rate for the 2020 benefit year and beyond are appropriate to incentivize issuers to control costs while improving risk prediction under the HHS risk adjustment models. Furthermore, we believe the $1 million threshold and 60 percent coinsurance rate will result in total high-cost risk pool payments or charges nationally that are very small as a percentage of premiums for issuers, and will prevent states and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk.

We also believe that maintaining the same threshold and coinsurance rate from year-to-year will help promote stability and predictability for issuers, and for all of these reasons, we are finalizing the $1 million threshold and 60 percent coinsurance rate for 2020 benefit year and beyond without requiring notice and comment on the high-cost risk pool thresholds each year. We intend to release information about the 2018 benefit year high-cost risk pool payment amounts, and the percent of premium charged by the high-cost risk pool in the 2018 benefit year summary risk adjustment report released under § 153.310(e), and would follow a similar approach for future benefit years. We appreciate the comments suggesting various potential changes to the high-cost risk pool methodology. Once we have results and experience from the initial years of the high-cost risk pool in the HHS risk adjustment program, we intend to analyze those results including considering the geographic variation within those results. If we were to seek to make changes to these parameters for benefit years beyond 2020, we would do so through notice-and-comment rulemaking prior to any changes being implemented.

We encourage states considering a state-based reinsurance program to consider the interplay between the high-cost risk pool adjustment in the HHS-operated risk adjustment program and any state-based reinsurance program. We have provided technical guidance to states considering state-based reinsurance programs to assist them in designing such programs in a manner that avoids double compensating for costs that would otherwise be compensated under the risk adjustment methodology, including the high-cost risk pool adjustment.

iv. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The factors resulting from the equally weighted blended factors from the 2015 MarketScan® data and the 2016 and 2017 enrollee-level EDGE data separately solved models, including the finalized constraints for the Hepatitis C RXC coefficient, are shown in Tables 1, 3, and 4. For the purposes of the below coefficients, the adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.

Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, and enrollment duration coefficients. Table 2 contains the HHS HCCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant model maturity and severity categories, respectively.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.149	0.117	0.079	0.043	0.039
	Age 25–29, Male	0.143	0.111	0.072	0.035	0.030
	Age 30–34, Male	0.170	0.131	0.085	0.039	0.033
	Age 35–39, Male	0.208	0.161	0.106	0.051	0.045
	Age 40–44, Male	0.251	0.198	0.136	0.074	0.067
	Age 45–49, Male	0.294	0.234	0.165	0.094	0.086
	Age 50–54, Male	0.381	0.311	0.229	0.144	0.134
	Age 55–59, Male	0.427	0.348	0.259	0.166	0.154
	Age 60–64, Male	0.476	0.386	0.286	0.180	0.167
	Age 21–24, Female	0.233	0.185	0.122	0.061	0.054
	Age 25–29, Female	0.263	0.208	0.139	0.070	0.061
	Age 30–34, Female	0.350	0.282	0.203	0.124	0.115
	Age 35–39, Female	0.422	0.346	0.261	0.177	0.167
	Age 40–44, Female	0.467	0.382	0.288	0.194	0.183
	Age 45–49, Female	0.478	0.389	0.289	0.188	0.175
	Age 50–54, Female	0.523	0.430	0.324	0.211	0.197
	Age 55–59, Female	0.501	0.407	0.299	0.185	0.171
	Age 60–64, Female	0.508	0.409	0.295	0.174	0.158
	Diagnosis Factors					
HCC001	HIV/AIDS	2.965	2.679	2.477	2.398	2.390

[27] 81 FR 94080.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.	7.468	7.261	7.144	7.172	7.180
HCC003	Central Nervous System Infections, Except Viral Meningitis.	5.477	5.397	5.344	5.361	5.363
HCC004	Viral or Unspecified Meningitis	4.437	4.230	4.106	4.022	4.012
HCC006	Opportunistic Infections	5.920	5.844	5.796	5.758	5.753
HCC008	Metastatic Cancer	21.104	20.616	20.288	20.316	20.320
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	10.886	10.539	10.306	10.268	10.263
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	5.254	5.018	4.850	4.768	4.757
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers.	3.851	3.620	3.454	3.369	3.358
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.502	2.333	2.208	2.127	2.116
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.108	0.981	0.874	0.754	0.738
HCC018	Pancreas Transplant Status/Complications.	4.008	3.806	3.686	3.681	3.682
HCC019	Diabetes with Acute Complications	0.470	0.406	0.345	0.281	0.273
HCC020	Diabetes with Chronic Complications	0.470	0.406	0.345	0.281	0.273
HCC021	Diabetes without Complication	0.470	0.406	0.345	0.281	0.273
HCC023	Protein-Calorie Malnutrition	11.139	11.127	11.117	11.204	11.215
HCC026	Mucopolysaccharidosis	2.368	2.269	2.192	2.130	2.122
HCC027	Lipidoses and Glycogenosis	2.368	2.269	2.192	2.130	2.122
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders.	2.368	2.269	2.192	2.130	2.122
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders.	2.368	2.269	2.192	2.130	2.122
HCC034	Liver Transplant Status/Complications.	9.422	9.331	9.272	9.246	9.242
HCC035	End-Stage Liver Disease	4.595	4.386	4.253	4.225	4.222
HCC036	Cirrhosis of Liver	1.282	1.152	1.065	0.999	0.991
HCC037_1	Chronic Viral Hepatitis C	0.847	0.741	0.667	0.594	0.586
HCC037_2	Chronic Hepatitis, Other/Unspecified	0.847	0.741	0.667	0.594	0.586
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis.	4.287	4.119	4.015	3.981	3.978
HCC041	Intestine Transplant Status/Complications.	31.374	31.347	31.328	31.345	31.346
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.	9.205	8.962	8.803	8.803	8.804
HCC045	Intestinal Obstruction	5.389	5.146	5.000	4.975	4.973
HCC046	Chronic Pancreatitis	4.008	3.806	3.686	3.681	3.682
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.028	1.869	1.761	1.675	1.664
HCC048	Inflammatory Bowel Disease	2.185	2.010	1.877	1.774	1.760
HCC054	Necrotizing Fasciitis	5.280	5.093	4.966	4.966	4.966
HCC055	Bone/Joint/Muscle Infections/Necrosis.	5.280	5.093	4.966	4.966	4.966
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders.	3.170	2.968	2.818	2.754	2.746
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders.	0.803	0.689	0.591	0.473	0.457
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies.	2.651	2.462	2.325	2.244	2.234
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders.	2.651	2.462	2.325	2.244	2.234
HCC063	Cleft Lip/Cleft Palate	1.841	1.676	1.561	1.476	1.467
HCC066	Hemophilia	60.165	59.790	59.521	59.527	59.526
HCC067	Myelodysplastic Syndromes and Myelofibrosis.	11.585	11.458	11.370	11.361	11.360
HCC068	Aplastic Anemia	11.585	11.458	11.370	11.361	11.360
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.	7.073	6.964	6.883	6.847	6.842
HCC070	Sickle Cell Anemia (Hb-SS)	7.073	6.964	6.883	6.847	6.842
HCC071	Thalassemia Major	7.073	6.964	6.883	6.847	6.842

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC073	Combined and Other Severe Immunodeficiencies.	4.606	4.478	4.394	4.381	4.379
HCC074	Disorders of the Immune Mechanism	4.606	4.478	4.394	4.381	4.379
HCC075	Coagulation Defects and Other Specified Hematological Disorders.	2.791	2.702	2.634	2.596	2.591
HCC081	Drug Psychosis	3.438	3.202	3.033	2.892	2.872
HCC082	Drug Dependence	3.438	3.202	3.033	2.892	2.872
HCC087	Schizophrenia	2.827	2.586	2.422	2.311	2.298
HCC088	Major Depressive and Bipolar Disorders.	1.602	1.438	1.313	1.184	1.167
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders.	1.589	1.433	1.312	1.183	1.165
HCC090	Personality Disorders	1.115	0.998	0.889	0.759	0.742
HCC094	Anorexia/Bulimia Nervosa	2.535	2.370	2.245	2.164	2.152
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.	5.275	5.178	5.108	5.049	5.040
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.351	1.255	1.177	1.105	1.096
HCC102	Autistic Disorder	1.127	1.009	0.899	0.771	0.754
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder.	1.115	0.998	0.889	0.759	0.742
HCC106	Traumatic Complete Lesion Cervical Spinal Cord.	10.383	10.248	10.157	10.135	10.131
HCC107	Quadriplegia	10.383	10.248	10.157	10.135	10.131
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord.	7.512	7.355	7.247	7.209	7.203
HCC109	Paraplegia	7.512	7.355	7.247	7.209	7.203
HCC110	Spinal Cord Disorders/Injuries	5.070	4.849	4.700	4.653	4.647
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.	1.804	1.606	1.474	1.372	1.360
HCC112	Quadriplegic Cerebral Palsy	0.073	0.036	0.009	0.000	0.000
HCC113	Cerebral Palsy, Except Quadriplegic	0.073	0.036	0.009	0.000	0.000
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.544	0.452	0.392	0.341	0.335
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.301	5.172	5.088	5.074	5.072
HCC117	Muscular Dystrophy	1.925	1.783	1.682	1.581	1.565
HCC118	Multiple Sclerosis	3.769	3.557	3.406	3.322	3.311
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	1.925	1.783	1.682	1.581	1.565
HCC120	Seizure Disorders and Convulsions	1.275	1.128	1.020	0.917	0.904
HCC121	Hydrocephalus	6.490	6.383	6.303	6.282	6.279
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage.	8.031	7.885	7.780	7.766	7.763
HCC125	Respirator Dependence/Tracheostomy Status.	24.882	24.831	24.794	24.883	24.894
HCC126	Respiratory Arrest	7.394	7.224	7.123	7.191	7.202
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	7.394	7.224	7.123	7.191	7.202
HCC128	Heart Assistive Device/Artificial Heart	27.608	27.411	27.286	27.322	27.328
HCC129	Heart Transplant	27.608	27.411	27.286	27.322	27.328
HCC130	Congestive Heart Failure	2.607	2.505	2.437	2.423	2.422
HCC131	Acute Myocardial Infarction	7.214	6.923	6.738	6.797	6.807
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease.	4.822	4.534	4.368	4.345	4.345
HCC135	Heart Infection/Inflammation, Except Rheumatic.	5.503	5.383	5.302	5.271	5.268
HCC142	Specified Heart Arrhythmias	2.479	2.340	2.237	2.159	2.149
HCC145	Intracranial Hemorrhage	7.332	7.062	6.890	6.848	6.844
HCC146	Ischemic or Unspecified Stroke	1.907	1.754	1.666	1.624	1.620
HCC149	Cerebral Aneurysm and Arteriovenous Malformation.	2.765	2.588	2.468	2.389	2.378
HCC150	Hemiplegia/Hemiparesis	4.362	4.253	4.188	4.232	4.240

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC151	Monoplegia, Other Paralytic Syndromes.	2.821	2.693	2.606	2.557	2.551
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene.	8.986	8.890	8.830	8.913	8.926
HCC154	Vascular Disease with Complications	6.374	6.218	6.114	6.091	6.088
HCC156	Pulmonary Embolism and Deep Vein Thrombosis.	3.333	3.184	3.082	3.013	3.004
HCC158	Lung Transplant Status/Complications.	22.628	22.505	22.423	22.495	22.505
HCC159	Cystic Fibrosis	6.673	6.414	6.226	6.203	6.200
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.	0.867	0.759	0.665	0.564	0.551
HCC161	Asthma	0.867	0.759	0.665	0.564	0.551
HCC162	Fibrosis of Lung and Other Lung Disorders.	1.918	1.813	1.742	1.688	1.680
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.343	6.311	6.288	6.291	6.292
HCC183	Kidney Transplant Status	6.355	6.161	6.035	5.970	5.965
HCC184	End Stage Renal Disease	25.179	24.922	24.750	24.897	24.939
HCC187	Chronic Kidney Disease, Stage 5	1.067	1.016	0.985	0.997	1.001
HCC188	Chronic Kidney Disease, Stage 4	1.067	1.016	0.985	0.997	1.001
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.003	0.868	0.740	0.542	0.512
HCC204	Miscarriage with Complications	1.003	0.868	0.740	0.542	0.512
HCC205	Miscarriage with No or Minor Complications.	1.003	0.868	0.740	0.542	0.512
HCC207	Completed Pregnancy With Major Complications.	3.296	2.892	2.678	2.344	2.301
HCC208	Completed Pregnancy With Complications.	3.296	2.892	2.678	2.344	2.301
HCC209	Completed Pregnancy with No or Minor Complications.	3.296	2.892	2.678	2.344	2.301
HCC217	Chronic Ulcer of Skin, Except Pressure.	1.908	1.800	1.730	1.702	1.700
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures.	8.274	8.044	7.894	7.911	7.913
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.	4.796	4.648	4.546	4.494	4.488
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications.	24.793	24.786	24.778	24.810	24.814
HCC253	Artificial Openings for Feeding or Elimination.	7.812	7.725	7.666	7.696	7.700
HCC254	Amputation Status, Lower Limb/Amputation Complications.	3.011	2.887	2.811	2.821	2.823
	Interaction Factors					
SEVERE x HCC006.	Severe illness x Opportunistic Infections.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC008.	Severe illness x Metastatic Cancer	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC009.	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC010.	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC115.	Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC135.	Severe illness x Heart Infection/Inflammation, Except Rheumatic.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC145.	Severe illness x Intracranial Hemorrhage.	7.044	7.251	7.387	7.555	7.575
SEVERE x G06	Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68).	7.044	7.251	7.387	7.555	7.575

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
SEVERE x G08 ...	Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74).	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC035.	Severe illness x End-Stage Liver Disease.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC038.	Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC153.	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC154.	Severe illness x Vascular Disease with Complications.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC163.	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC253.	Severe illness x Artificial Openings for Feeding or Elimination.	0.873	0.935	0.977	1.119	1.136
SEVERE x G03 ...	Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55).	0.873	0.935	0.977	1.119	1.136
	Enrollment Duration Factors					
	1 month of enrollment	0.316	0.276	0.247	0.232	0.230
	2 months of enrollment	0.302	0.263	0.234	0.219	0.218
	3 months of enrollment	0.278	0.241	0.213	0.199	0.197
	4 months of enrollment	0.241	0.208	0.179	0.165	0.164
	5 months of enrollment	0.217	0.188	0.162	0.148	0.147
	6 months of enrollment	0.185	0.160	0.137	0.123	0.122
	7 months of enrollment	0.152	0.131	0.111	0.099	0.098
	8 months of enrollment	0.118	0.103	0.088	0.079	0.078
	9 months of enrollment	0.074	0.064	0.054	0.048	0.048
	10 months of enrollment	0.035	0.032	0.030	0.029	0.029
	11 months of enrollment	0.030	0.028	0.027	0.027	0.027
	Prescription Drug Factors					
RXC 01	Anti-HIV Agents	6.528	5.936	5.505	5.164	5.120
RXC 02	Anti-Hepatitis C (HCV) Agents	8.369	7.752	7.359	7.413	7.430
RXC 03	Antiarrhythmics	0.116	0.112	0.109	0.096	0.090
RXC 04	Phosphate Binders	1.927	1.924	1.918	1.904	1.862
RXC 05	Inflammatory Bowel Disease Agents	1.746	1.591	1.470	1.293	1.266
RXC 06	Insulin	1.796	1.630	1.453	1.254	1.227
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only.	0.644	0.547	0.452	0.315	0.296
RXC 08	Multiple Sclerosis Agents	18.819	17.877	17.252	17.101	17.067
RXC 09	Immune Suppressants and Immunomodulators.	12.688	12.085	11.697	11.770	11.783
RXC 10	Cystic Fibrosis Agents	12.240	11.876	11.659	11.708	11.717
RXC 01 x HCC001.	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	0.273	0.520	0.735	1.187	1.247
RXC 02 x HCC037_1, 036, 035, 034.	Additional effect for enrollees with RXC 02 (Anti-Hepatitis C (HCV) Agents) and (HCC 037_1 (Chronic Viral Hepatitis C) or 036 (Cirrhosis of Liver) or 035 (End-Stage Liver Disease) or 034 (Liver Transplant Status/Complications)).	-0.156	0.043	0.168	0.300	0.311
RXC 03 x HCC142.	Additional effect for enrollees with RxC 03 (Antiarrhythmics) and HCC 142 (Specified Heart Arrhythmias).	0.000	0.000	0.000	0.000	0.000

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 04 x HCC184, 183, 187, 188.	Additional effect for enrollees with RxC 04 (Phosphate Binders) and (HCC 184 (End Stage Renal Disease) or 183 (Kidney Transplant Status) or 187 (Chronic Kidney Disease, Stage 5) or 188 (Chronic Kidney Disease, Severe Stage 4)).	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041.	Additional effect for enrollees with RxC 05 (Inflammatory Bowel Disease Agents) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	-0.820	-0.761	-0.692	-0.635	-0.626
RXC 06 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 06 (Insulin) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	0.289	0.247	0.309	0.355	0.360
RXC 07 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 07 (Anti-Diabetic Agents, Except Insulin and Metformin Only) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	-0.303	-0.259	-0.209	-0.169	-0.164
RXC 08 x HCC118.	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	-1.409	-0.898	-0.556	-0.216	-0.157
RXC 09 x HCC056 or 057 and 048 or 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)) and (HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders) or 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders)).	0.536	0.652	0.731	0.831	0.844
RXC 09 x HCC056.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	-3.170	-2.968	-2.818	-2.754	-2.746
RXC 09 x HCC057.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders).	-0.803	-0.689	-0.545	-0.428	-0.411
RXC 09 x HCC048, 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	-0.783	-0.621	-0.528	-0.439	-0.427
RXC 10 x HCC159, 158.	Additional effect for enrollees with RxC 10 (Cystic Fibrosis Agents) and (HCC 159 (Cystic Fibrosis) or 158 (Lung Transplant Status/Complications)).	38.322	38.485	38.558	38.691	38.706

TABLE 2—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE

HCC/description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Peritonitis/Gastrointestinal Perforation/Necrotizing Entercolitis
Seizure Disorders and Convulsions
Non-Traumatic Coma, Brain Compression/Anoxic Damage
Respirator Dependence/Tracheostomy Status
Respiratory Arrest
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Pulmonary Embolism and Deep Vein Thrombosis

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.201	0.156	0.105	0.060	0.054
Age 5–9, Male	0.141	0.105	0.064	0.031	0.028
Age 10–14, Male	0.178	0.141	0.094	0.058	0.055
Age 15–20, Male	0.231	0.186	0.132	0.084	0.079
Age 2–4, Female	0.153	0.115	0.074	0.041	0.037
Age 5–9, Female	0.097	0.068	0.034	0.009	0.008
Age 10–14, Female	0.169	0.133	0.090	0.058	0.055
Age 15–20, Female	0.251	0.197	0.130	0.069	0.063
Diagnosis Factors					
HIV/AIDS	4.444	4.000	3.704	3.571	3.553
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	12.684	12.483	12.370	12.357	12.358
Central Nervous System Infections, Except Viral Meningitis	7.639	7.474	7.370	7.375	7.376
Viral or Unspecified Meningitis	3.537	3.306	3.162	2.985	2.961
Opportunistic Infections	14.897	14.855	14.821	14.803	14.798
Metastatic Cancer	33.549	33.307	33.125	33.137	33.137
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.316	9.063	8.873	8.780	8.769
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	7.430	7.181	6.996	6.883	6.868
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.288	3.116	2.980	2.862	2.844
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.288	3.116	2.980	2.862	2.844
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.971	0.848	0.742	0.624	0.608
Pancreas Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Diabetes with Acute Complications	2.562	2.227	2.024	1.732	1.695
Diabetes with Chronic Complications	2.562	2.227	2.024	1.732	1.695
Diabetes without Complication	2.562	2.227	2.024	1.732	1.695
Protein-Calorie Malnutrition	13.857	13.753	13.679	13.719	13.724
Mucopolysaccharidosis	6.541	6.316	6.146	6.097	6.090
Lipidoses and Glycogenosis	6.541	6.316	6.146	6.097	6.090
Congenital Metabolic Disorders, Not Elsewhere Classified	6.541	6.316	6.146	6.097	6.090
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.541	6.316	6.146	6.097	6.090
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.541	6.316	6.146	6.097	6.090
Liver Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
End-Stage Liver Disease	16.546	16.340	16.213	16.213	16.213
Cirrhosis of Liver	3.126	3.000	2.914	2.887	2.887
Chronic Viral Hepatitis C	2.946	2.800	2.696	2.677	2.679
Chronic Hepatitis, Other/Unspecified	0.565	0.486	0.438	0.412	0.409
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.172	11.066	11.000	11.024	11.029
Intestine Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.360	11.054	10.851	10.833	10.833
Intestinal Obstruction	4.422	4.220	4.069	3.964	3.951
Chronic Pancreatitis	12.558	12.300	12.130	12.111	12.111
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.280	2.164	2.067	1.971	1.957
Inflammatory Bowel Disease	7.491	7.076	6.790	6.672	6.656
Necrotizing Fasciitis	3.884	3.665	3.504	3.422	3.412
Bone/Joint/Muscle Infections/Necrosis	3.884	3.665	3.504	3.422	3.412
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.147	3.898	3.705	3.613	3.602

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.707	0.589	0.478	0.367	0.355
Osteogenesis Imperfecta and Other Osteodystrophies	1.308	1.197	1.101	1.020	1.009
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.308	1.197	1.101	1.020	1.009
Cleft Lip/Cleft Palate	1.309	1.130	0.998	0.869	0.853
Hemophilia	63.672	63.119	62.729	62.694	62.689
Myelodysplastic Syndromes and Myelofibrosis	14.847	14.726	14.643	14.617	14.613
Aplastic Anemia	14.847	14.726	14.643	14.617	14.613
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.690	6.486	6.338	6.255	6.246
Sickle Cell Anemia (Hb-SS)	6.690	6.486	6.338	6.255	6.246
Thalassemia Major	6.690	6.486	6.338	6.255	6.246
Combined and Other Severe Immunodeficiencies	5.228	5.082	4.975	4.916	4.908
Disorders of the Immune Mechanism	5.228	5.082	4.975	4.916	4.908
Coagulation Defects and Other Specified Hematological Disorders	4.562	4.439	4.341	4.263	4.253
Drug Psychosis	5.378	5.097	4.918	4.827	4.816
Drug Dependence	5.378	5.097	4.918	4.827	4.816
Schizophrenia	4.720	4.358	4.111	3.955	3.935
Major Depressive and Bipolar Disorders	2.523	2.294	2.112	1.933	1.909
Reactive and Unspecified Psychosis, Delusional Disorders	2.437	2.219	2.042	1.864	1.841
Personality Disorders	0.505	0.407	0.299	0.163	0.145
Anorexia/Bulimia Nervosa	2.473	2.274	2.118	2.023	2.009
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	1.577	1.426	1.324	1.254	1.244
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.523	1.376	1.270	1.181	1.169
Autistic Disorder	2.419	2.205	2.030	1.859	1.836
Pervasive Developmental Disorders, Except Autistic Disorder	0.522	0.436	0.337	0.218	0.203
Traumatic Complete Lesion Cervical Spinal Cord	9.975	9.927	9.898	9.978	9.989
Quadriplegia	9.975	9.927	9.898	9.978	9.989
Traumatic Complete Lesion Dorsal Spinal Cord	7.111	6.894	6.752	6.717	6.710
Paraplegia	7.111	6.894	6.752	6.717	6.710
Spinal Cord Disorders/Injuries	3.688	3.501	3.361	3.265	3.251
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	15.639	15.397	15.212	15.129	15.117
Quadriplegic Cerebral Palsy	2.136	1.935	1.829	1.823	1.824
Cerebral Palsy, Except Quadriplegic	0.189	0.141	0.109	0.080	0.076
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.317	1.190	1.100	1.029	1.020
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.492	10.315	10.194	10.192	10.192
Muscular Dystrophy	3.105	2.925	2.800	2.692	2.679
Multiple Sclerosis	9.585	9.204	8.943	8.908	8.904
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.105	2.925	2.800	2.692	2.679
Seizure Disorders and Convulsions	1.998	1.839	1.701	1.554	1.535
Hydrocephalus	4.263	4.146	4.066	4.043	4.041
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	5.460	5.327	5.226	5.177	5.170
Respirator Dependence/Tracheostomy Status	31.764	31.644	31.579	31.727	31.745
Respiratory Arrest	9.892	9.639	9.484	9.442	9.437
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	9.892	9.639	9.484	9.442	9.437
Heart Assistive Device/Artificial Heart	22.808	22.525	22.334	22.355	22.358
Heart Transplant	22.808	22.525	22.334	22.355	22.358
Congestive Heart Failure	5.721	5.612	5.528	5.484	5.477
Acute Myocardial Infarction	5.658	5.556	5.512	5.497	5.494
Unstable Angina and Other Acute Ischemic Heart Disease	4.360	4.255	4.196	4.165	4.163
Heart Infection/Inflammation, Except Rheumatic	12.103	11.996	11.921	11.912	11.912
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.989	3.841	3.696	3.585	3.569
Major Congenital Heart/Circulatory Disorders	1.271	1.172	1.054	0.940	0.927
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.828	0.738	0.638	0.551	0.541
Specified Heart Arrhythmias	3.678	3.514	3.378	3.301	3.291
Intracranial Hemorrhage	12.336	12.112	11.968	11.959	11.960
Ischemic or Unspecified Stroke	4.916	4.834	4.788	4.787	4.788
Cerebral Aneurysm and Arteriovenous Malformation	3.106	2.925	2.803	2.713	2.701

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Hemiplegia/Hemiparesis	4.229	4.100	4.016	3.960	3.952
Monoplegia, Other Paralytic Syndromes	2.907	2.753	2.650	2.591	2.582
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.094	11.845	11.673	11.607	11.596
Vascular Disease with Complications	11.883	11.747	11.650	11.669	11.670
Pulmonary Embolism and Deep Vein Thrombosis	15.067	14.952	14.883	14.915	14.920
Lung Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Cystic Fibrosis	22.808	22.525	22.334	22.355	22.358
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.373	0.307	0.222	0.134	0.123
Asthma	0.373	0.307	0.222	0.134	0.123
Fibrosis of Lung and Other Lung Disorders	2.327	2.232	2.140	2.066	2.058
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.863	6.796	6.748	6.770	6.772
Kidney Transplant Status	10.610	10.344	10.176	10.122	10.115
End Stage Renal Disease	32.082	31.966	31.885	31.983	31.998
Chronic Kidney Disease, Stage 5	3.813	3.698	3.607	3.511	3.502
Chronic Kidney Disease, Severe (Stage 4)	3.813	3.698	3.607	3.511	3.502
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	0.929	0.782	0.635	0.417	0.386
Miscarriage with Complications	0.929	0.782	0.635	0.417	0.386
Miscarriage with No or Minor Complications	0.929	0.782	0.635	0.417	0.386
Completed Pregnancy With Major Complications	2.848	2.472	2.253	1.879	1.824
Completed Pregnancy With Complications	2.848	2.472	2.253	1.879	1.824
Completed Pregnancy with No or Minor Complications	2.848	2.472	2.253	1.879	1.824
Chronic Ulcer of Skin, Except Pressure	2.720	2.626	2.539	2.464	2.456
Hip Fractures and Pathological Vertebral or Humerus Fractures	6.385	6.075	5.850	5.736	5.724
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.954	1.797	1.655	1.504	1.483
Stem Cell, Including Bone Marrow, Transplant Status/ Complications	22.808	22.525	22.334	22.355	22.358
Artificial Openings for Feeding or Elimination	11.222	11.090	11.022	11.127	11.143
Amputation Status, Lower Limb/Amputation Complications	5.244	4.993	4.817	4.689	4.670

TABLE 4—INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	242.262	240.657	239.483	239.461	239.461
Extremely Immature * Severity Level 4	148.994	147.251	145.979	145.799	145.783
Extremely Immature * Severity Level 3	34.940	33.753	32.859	32.577	32.555
Extremely Immature * Severity Level 2	34.940	33.753	32.859	32.577	32.555
Extremely Immature * Severity Level 1 (Lowest)	34.940	33.753	32.859	32.577	32.555
Immature * Severity Level 5 (Highest)	149.437	147.839	146.672	146.625	146.621
Immature * Severity Level 4	71.066	69.513	68.370	68.254	68.240
Immature * Severity Level 3	33.916	32.618	31.662	31.423	31.400
Immature * Severity Level 2	24.559	23.305	22.377	22.064	22.026
Immature * Severity Level 1 (Lowest)	24.559	23.305	22.377	22.064	22.026
Premature/Multiples * Severity Level 5 (Highest)	113.849	112.409	111.366	111.243	111.232
Premature/Multiples * Severity Level 4	26.707	25.337	24.357	24.088	24.061
Premature/Multiples * Severity Level 3	13.625	12.592	11.834	11.346	11.287
Premature/Multiples * Severity Level 2	8.285	7.520	6.882	6.224	6.128
Premature/Multiples * Severity Level 1 (Lowest)	5.381	4.835	4.284	3.704	3.632
Term * Severity Level 5 (Highest)	87.084	85.832	84.905	84.690	84.663
Term * Severity Level 4	13.879	12.979	12.323	11.859	11.806
Term * Severity Level 3	5.728	5.171	4.646	4.042	3.959
Term * Severity Level 2	3.614	3.188	2.691	2.051	1.970
Term * Severity Level 1 (Lowest)	1.596	1.375	0.973	0.579	0.544
Age1 * Severity Level 5 (Highest)	57.825	57.074	56.512	56.400	56.389
Age1 *Severity Level 4	10.546	10.003	9.561	9.255	9.219
Age1 * Severity Level 3	3.013	2.744	2.491	2.267	2.241
Age1 * Severity Level 2	1.880	1.673	1.452	1.219	1.191
Age1 * Severity Level 1 (Lowest)	0.515	0.455	0.374	0.314	0.307
Age 0 Male	0.646	0.595	0.560	0.489	0.478
Age 1 Male	0.120	0.106	0.093	0.073	0.070

TABLE 5—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birth weight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.
Immature	Premature Newborns, Including Birth weight 1000–1499 Grams.
Immature	Premature Newborns, Including Birth weight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
Age 1	All age 1 infants.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC/description
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC/description
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

v. Cost-Sharing Reduction Adjustments

We proposed to continue including an adjustment for the receipt of cost-sharing reductions (CSRs) in the risk adjustment models to account for increased plan liability due to increased utilization of health care services by enrollees receiving CSRs in all 50 states and the District of Columbia. For the 2020 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019 Payment Notice.[28] See Table 7.

Consistent with the approach finalized in the 2017 Payment Notice,[29] we also proposed to continue to use CSR adjustment factors of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have actuarial values above 94 percent. We are finalizing the CSR adjustment as proposed.

[28] See 83 FR 16930 at 16953.

[29] See 81 FR 12203 at 12228.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

Comment: Commenters supported the proposal that the CSR adjustments be consistent with those finalized in the 2019 Payment Notice. One commenter recommended that if HHS contemplates changing these factors for future benefit years, HHS should publish a white paper prior to rulemaking to provide issuers an advance opportunity to review and comment on the proposed approach. One commenter requested that HHS assess the impact of these factors and consider the possibility that issuers with a lower distribution of silver plan enrollees may be negatively impacted. One commenter supported continuing to use the CSR factor of 1.12 for Massachusetts' wrap-around coverage.

Response: We are finalizing the CSR adjustment as proposed. We intend to continue to review the enrollee-level EDGE data, including the distribution of enrollees by metal tier, to assess whether changes to these factors are needed. If we were to consider changes to the CSR adjustment in the future, we would do so through notice-and-comment rulemaking.

vi. Model Performance Statistics

To evaluate risk adjustment model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios also measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly will have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.[30] The final R-squared statistic for each model that is shown in Table 8 reflects the results from each dataset used in the separately solved models that are used to recalibrate the models for the 2020 benefit year, namely the 2015 MarketScan® data, and the 2016 and 2017 enrollee-level EDGE data.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

Models	2016 Enrollee level EDGE data	2017 Enrollee-level EDGE data R-squared	2015 MarketScan® data R-squared
Platinum Adult	0.4189	0.4131	0.4120
Gold Adult	0.4131	0.4065	0.4065
Silver Adult	0.4084	0.4011	0.4023
Bronze Adult	0.4052	0.3974	0.3996
Catastrophic Adult	0.4047	0.3968	0.3991
Platinum Child	0.3109	0.3252	0.3330
Gold Child	0.3062	0.3201	0.3283
Silver Child	0.3022	0.3157	0.3244
Bronze Child	0.2986	0.3118	0.3207
Catastrophic Child	0.2981	0.3112	0.3201
Platinum Infant	0.3257	0.3168	0.3331
Gold Infant	0.3217	0.3127	0.3310

[30] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries. April 2007.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS—Continued

Models	2016 Enrollee level EDGE data	2017 Enrollee-level EDGE data R-squared	2015 MarketScan® data R-squared
Silver Infant	0.3188	0.3096	0.3297
Bronze Infant	0.3172	0.3079	0.3294
Catastrophic Infant	0.3170	0.3077	0.3294

b. Overview of the Risk Adjustment Transfer Methodology (§ 153.320)

We defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.[31] The risk adjustment transfer methodology (state transfer formula payments and charges and high-cost risk pool payments and charges) is applied after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. The state payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, we calculate separate transfer amounts for each rating area in which a risk adjustment covered plan operates).

The risk adjustment state payment transfer formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount based on the statewide average premium. HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average risk in a budget-neutral manner. This approach supports the overall goals of the risk adjustment program, which are to encourage issuers to rate for the average risk in the applicable state market risk pool, to stabilize premiums, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefit designs or create marketing strategies to avoid high-risk enrollees. Such incentives could arise if we used each issuer's plan's own premium in the risk adjustment state payment transfer formula, instead of statewide average premium.

In the absence of additional funding, we established through notice-and-comment rulemaking[32] the HHS-operated risk adjustment program as a budget-neutral program to provide certainty to issuers regarding risk adjustment payments and charges, which allows issuers to set rates based on those expectations. Adopting an approach that would not result in balanced payments and charges would create considerable uncertainty for issuers regarding the proportion of risk adjustment payments they could expect to receive. Additionally, in establishing the HHS-operated risk adjustment program, we could not have relied on the potential availability of general appropriation funds without creating the same uncertainty for issuers in the amount of risk adjustment payments they could expect, or reducing funding available for other programs. Relying on each year's budget process also would have required us to delay setting the parameters for any risk adjustment payment proration rates until well after the plans were in effect for the applicable benefit year. HHS also could not have relied on any potential state budget appropriations in states that elected to operate a state-based risk adjustment program, as such funds would not be available for purposes of administering the HHS-operated risk adjustment program. Without the adoption of a budget-neutral framework, HHS would need to assess a charge or otherwise collect additional funds to avoid prorating risk adjustment payments. The resulting uncertainty would have also conflicted with the overall goals of the risk adjustment program—to stabilize premiums and reduce incentives for issuers to avoid enrolling individuals with higher-than-average actuarial risk.

In light of the budget-neutral framework, HHS uses statewide average premium as the cost-scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan's own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year. As set forth in prior discussions,[33] use of a plan's own premium or a similar parameter would have required a balancing adjustment in light of the program's need for budget neutrality—either through reducing payments to issuers owed a payment, increasing charges on issuers assessed a charge, or splitting the difference in some fashion between issuers owed payments and issuers assessed charges. Such adjustments would have impaired the risk adjustment program's goals of encouraging issuers to rate for the average risk in the applicable state market risk pool, stabilizing premiums, and avoiding the creation of incentives

[31] The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

[32] For example, see Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Final Rule, 77 FR 17232 (March 23, 2012); and the 2014 Payment Notice, Final Rule, 78 FR 15441 (March 11, 2013). Also see, the 2018 Payment Notice, Final Rule, 81 FR 94058 (December 22, 2016); and the 2019 Payment Notice, Final Rule, 83 FR 16930 (April 17, 2018). Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (December 10, 2018).

[33] For example, see September 12, 2011, *Risk Adjustment Implementation Issues* White Paper, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf*. Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (December 10, 2018).

for issuers to operate less efficiently, set higher prices, develop benefit designs or create marketing strategies to avoid higher-risk enrollees. Adoption of a methodology that would require use of an after-the-fact balancing adjustment is also less predictable for issuers than a methodology that is established in advance of a benefit year. Stakeholders who support use of a plan's own premium state that use of statewide average premium penalizes issuers with efficient care management. While effective care management may make a plan more likely to have lower costs,[34] we do not believe that care management strategies make the plan more likely to enroll lower-than-average risk enrollees; effective care management strategies might even make the plan more likely to attract higher-than-average risk enrollees, in which case the plan will benefit from the use of statewide average premium in the state payment transfer formula in the HHS risk adjustment methodology. As noted by commenters to the 2014 Payment Notice proposed rule, transfers may also be more volatile from year to year and sensitive to anomalous premiums if scaled to a plan's own premium instead of the statewide average premium. In all, the advantages of using statewide average premium outweigh the pricing instability and other challenges associated with calculating transfers based on a plan's own premium.

In the HHS risk adjustment transfer methodology, the state payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the state payment transfer formula is multiplied by each plan's total billable member months for the applicable benefit year to determine the payment due to or charge owed by the issuer for that plan in a rating area. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

Although we did not seek comment on this topic, we summarize and respond to the comments on statewide average premium and plan's own premium received in response to the proposed rule below. Given the volume of exhibits, court filings, white papers (including all corresponding exhibits), and comments on other rulemakings incorporated by reference, we are not able to separately address each of those documents. Instead, we summarize and respond to the significant comments and issues raised by the commenters that are within the scope of this rulemaking.

Comment: Some commenters expressed support for the operation of the HHS risk adjustment program in a budget-neutral manner and the utilization of statewide average premium as the cost-scaling factor to ensure that issuers' collection amounts equal payment amounts for the applicable benefit year. These commenters noted that use of statewide average premium results in balanced payment transfers in a state market risk pool and helps advance the market stabilizing goals of the risk adjustment program, and they supported maintaining the current risk adjustment state payment transfer formula and the budget neutral framework.

Some commenters opposed the use of statewide average premiums. These commenters stated that the current risk adjustment state payment transfer formula's use of statewide average premiums penalizes efficient plans, and is a biased estimate of enrollee medical costs and actuarial risk that perversely penalize efficient, high-performing issuers. These commenters requested that HHS adopt alternatives to the existing risk adjustment methodology. One commenter supported the use of each plan's own premium as the cost scaling factor. This commenter stated that the risk adjustment state payment transfer formula does not need to operate as budget neutral, as section 1343 of the PPACA does not require that the program be budget neutral, and funds are available to HHS for the risk adjustment program from the CMS Program Management account to offset any potential shortfalls. The commenter also disagreed with HHS' rationale for using statewide average premium to achieve budget neutrality, and stated that even if budget neutrality is required, any risk adjustment payment shortfalls that may result from using a plan's own premium in the state payment transfer formula could be addressed through pro rata adjustments to risk adjustment transfers. This commenter further stated that use of statewide average premium is not predictable for issuers trying to set rates and compared the predicted risk adjustment results issuers set out in their respective rate filings with HHS' published actual risk adjustment results for a state, concluding that the risk adjustment program is failing to achieve its goal because its analysis found that issuers are failing to accurately forecast their risk adjustment results in their rate filings.

Conversely, other commenters expressed concerns about alternatives to statewide average premium. One commenter specifically opposed using a plan's own premium stating that it would undermine the risk adjustment program, create incentives for issuers to avoid enrolling high-cost individuals, and would not automatically balance transfers to zero. This commenter noted that the PPACA's risk adjustment statute requires states, or HHS on behalf of the states, to assess a charge on plans with lower than the average actuarial risk in the state market risk pool, and to make payments to plans with higher than the average actuarial risk in the state market risk pool. This commenter also agreed that absent Congressional action to appropriate additional funds, the risk adjustment program must operate in a budget-neutral manner. Additionally, the commenter concurred that if HHS were to require states operating their own risk adjustment programs to operate the programs to cover any shortfall between collections and payments for a benefit year, HHS would be effectively imposing an unfunded mandate on states. This commenter noted that analyses by the American Academy of Actuaries and Oliver Wyman indicated that the risk adjustment program is working as intended by compensating issuers that enroll higher-than-average risk enrollees and protecting against adverse selection.

Response: We agree that the use of statewide average premium supports the underlying goals of the risk adjustment program by discouraging the creation of benefit designs and marketing strategies to avoid high-risk enrollees and promoting market stability and predictability. The benefits of using statewide average premium as the cost scaling factor in the HHS risk adjustment state payment transfer formula therefore extend beyond its role in maintaining the budget neutrality of the program. Consistent with the statute, under the HHS-operated risk adjustment program, each risk adjustment covered plan in the state market risk pool receives a risk adjustment payment or owes a charge based on the plan's risk compared to the average risk in the state market risk pool. The statewide average premium reflects the average cost and efficiency level and was chosen as the cost scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology for a number of reasons. More specifically, HHS chose to use statewide average premium to encourage issuers to rate for the average risk, to automatically achieve equality between

[34] There are many reasons why an issuer could have lower-than-average premiums. For example, the low premium could be the result of efficiency, mispricing, a strategy to gain market share, or some combination thereof.

risk adjustment payments and charges in each benefit year, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefits designs or create marketing strategies to avoid high-risk enrollees. HHS considered and again declined in the 2018 and 2019 Payment Notices [35] and in the Adoption of the Methodology for the HHS-operated Permanent Risk Adjustment Program for the 2017 Benefit Year Final Rule (2017 Risk Adjustment Final Rule) [36] and Adoption of the Methodology for the HHS-operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule (2018 Risk Adjustment Final Rule) [37] to adopt the use of each plan's own premium in the state payment transfer formula.

As we detailed in the 2018 Payment Notice and the 2017 and 2018 Risk Adjustment Final Rules,[38] use of a plan's own premium would likely lead to substantial volatility in transfer results, and could result in even higher transfer charges for low-risk, low-premium plans because of the program's budget neutral framework. In addition, use of plan's own premium in a budget neutral program would require even greater transfer payments to high-risk, high-premium plans. Furthermore, use of a plan's own premium in the HHS formula would actually disadvantage high-risk, low-premium plans, or plans that some commenters referred to as the ''efficient plans,'' by undercompensating them based on their lower average premiums, which, in turn, could incentivize such plans to inflate premium prices to receive more favorable risk adjustment transfers along with increased premium revenue. If HHS instead applied a balancing adjustment to the state payment transfer formula in favor of these plans, low-risk, low-premium plans would be required to pay an even higher percentage of their plan-specific premiums in risk adjustment transfer charges due to the need to maintain the program's budget neutrality. This type of balancing adjustment would also result in a reduction to payments to high-risk, low-premium plans that are presumably more efficient than high-risk, high-premium plans, further incentivizing such plans to inflate premiums as described above. In other words, the use of a plan's own premium in the HHS program would neither reduce risk adjustment charges for low-cost and low-risk issuers, nor would it incentivize issuers to operate at the average efficiency. The application of a balancing adjustment in favor of low-risk, low-premium plans could under-compensate high-risk plans, increasing the likelihood that such plans would raise premiums. In addition, if the application of a balancing adjustment was split equally between high-risk and low-risk plans, such an adjustment would incentivize issuers to increase premiums or to employ risk-avoidance techniques. Finally, any such balancing adjustments would have to be determined after state transfers had been calculated, because an approach that uses the plan's own premium to calculate transfers would not necessarily result in budget-neutral transfers without a separate after-the-fact adjustment. As detailed above, such after-the-fact adjustments would impair the goals of the risk adjustment program and be less predictable for issuers. For all of these reasons, we previously declined and continue to decline to use each plan's own premium and are maintaining use of statewide average premium as the cost-scaling factor in the state payment transfer formula.

Comments: One commenter requested that HHS include a care management factor in the risk adjustment methodology, such as the care management effectiveness index (CME index) developed by Axene Health Partners, as this commenter believed that a care coordination factor would mitigate the impact of using statewide average premiums for issuers that successfully perform care management and improve health. This commenter stated that HHS represented in previous rulemaking that it could consider using the CME index in future years and encouraged HHS to follow through on that promise. Another commenter requested that HHS explore how plans with low administrative costs or high quality scores based on objective criteria and high-performing networks could be rewarded. One commenter stated that HHS' position in the proposed rule that it did ''not believe that the care management strategies make the plan more likely to enroll lower-than-average risk enrollees; effective care management strategies might even make the plan more likely to attract higher-than-average risk enrollees, in which case the plan would benefit from the use of statewide average premium in the state payment transfer formula in the HHS risk adjustment methodology'' was based on a faulty premise. This commenter stated that, in addition to care management strategies, the breadth of the plan's provider network has significant impact on price, and that, through the state payment transfer formula, enrollees who choose narrow networks subsidize plans from dominant issuers that can tend to have larger networks and higher prices. This commenter viewed this as a detrimental effect of the state payment transfer formula on plans with enrollees that choose narrow networks.

Some comments suggested proposed improvements to the HHS risk adjustment program generally. A few commenters expressed a desire for broad risk adjustment changes, including an exemption for new and fast-growing plans from risk adjustment for 3 to 5 years, applying a credibility-based approach to participation in risk adjustment based on membership size or market share, and placing an upper bound on the amount of a plan's risk adjustment transfer charge or using two-stage adult models that HHS proposed in the 2018 Payment Notice proposed rule. One commenter suggested HHS look at steps some states have taken to correct market distortions and consider the possibility of incorporating similar changes into the HHS risk adjustment models and state payment transfer formula. One commenter noted that HHS is aware of risk adjustment bias, has acknowledged its distortion, and has ignored the ''fix'' to switch the risk scores that were used by HHS with risk scores that more accurately represent the actual HCC costs or adopt another model that would eliminate estimated bias. This commenter also suggested HHS give states the option, at their discretion, to use a graduated cap on risk adjustment charges to reduce volatility and increase predictability of results, to establish a cap based on a percentage of premium to protect small issuers from the impact of large risk adjustment charges, or to allow states to consider structures in which caps shift at smaller more graduated intervals based on issuer size, to lower the risk that small enrollment shifts will tip an issuer between various caps.

Response: We appreciate the feedback on proposed updates to the HHS risk adjustment program. As we have noted, we remain committed to evaluating the program and engaging stakeholders in the program's policy development. We continue to regularly assess whether the HHS-operated risk adjustment program should be modified based on analysis of more recent data and changes (if any) in market dynamics, while weighing the tradeoffs of refinements with continuing to provide stability and predictability. Throughout this rule, we have identified several specific risk adjustment topics

[35] 81 FR 94100 and 83 FR 16930.

[36] 83 FR 36456.

[37] 83 FR 63419.

[38] 81 FR at 94100; 83 FR at 36458; and 83 FR at 63425.

we are currently assessing, anticipate seeking stakeholder feedback on, and may contemplate changes for future benefit years through notice-and-comment rulemaking.

We continuously evaluate whether improvements are needed to the HHS risk adjustment methodology, and will continue to do so as additional years' data become available. For example, beginning with the 2018 benefit year, we adopted a 14 percent reduction to the statewide average premium to account for administrative costs that are unrelated to the claims risk of the enrollee population.[39] While low cost plans are not necessarily efficient plans,[40] we believe this adjustment differentiates between premiums that reflect savings resulting from administrative efficiency from premiums that reflect healthier-than-average enrollees. HHS also modified the risk adjustment methodology beginning with the 2018 benefit year by incorporating a high-cost risk pool adjustment to mitigate residual incentives for risk selection to avoid high-cost enrollees, to better account for the average risk associated with the factors used in the HHS risk adjustment models, and to ensure that the actuarial risk of a plan with high-cost enrollees is better reflected in transfers to issuers with high actuarial risk.[41] Other recent changes made to the HHS risk adjustment program include the incorporation of a partial year adjustment factor and prescription drug utilization factors.[42]

However, at this time, we decline to amend the risk adjustment methodology to include a CME index or a similar care coordination adjustment. As we previously noted,[43] a change of this magnitude requires significant study and evaluation. Although this type of change is not feasible at present, we will continue to examine the feasibility, specificity, and sensitivity of measuring care management effectiveness through enrollee-level EDGE data for the individual, small group, and merged markets, and the benefits of incorporating such measures in the HHS risk adjustment transfer methodology in future benefit years, either through future rulemaking or other opportunities in which the public can submit comments. We believe that a robust risk adjustment program encourages issuers to improve care management effectiveness, as doing so would reduce plans' medical costs. As we explain above, use of statewide average premium in the HHS risk adjustment state payment transfer formula incentivizes plans to apply effective care management techniques to reduce losses, whereas use of a plan's own premium could be inflationary as it benefits plans with higher-than-average costs and premiums. While effective care management may make a plan more likely to have lower costs and premiums, we do not believe that care management strategies necessarily make the plan more likely to enroll lower-than-average risk enrollees. As we noted in the proposed rule, implementation of effective care management strategies may particularly attract high-risk enrollees with complex conditions that incur repeat utilization of services.

In addition, there are many reasons why an issuer could have lower-than-average premiums. For example, the low premium could be the result of efficiency, mispricing, a strategy to gain market share, or some combination thereof. As such, we disagree with the comment that the risk adjustment state payment transfer formula unfairly results in enrollees that choose narrow networks subsidizing enrollees in broader networks, including enrollees in plans issued by dominant carriers. Networks are just one of many plan design characteristics that are captured through the use of the statewide average premium in the state payment transfer formula, which is designed to discourage the creation of plan designs and marketing strategies to avoid high-risk enrollees, in keeping with the goals of the risk adjustment program. Thus, to the extent certain plan network designs attract sicker-than-average enrollees, the risk adjustment program assesses the level of risk and compensates those plans for the incremental risk.

We have previously considered other model changes, including the adoption of a two-stage adult model. Specifically, as discussed in the 2018 Payment Notice proposed rule,[44] we considered the use of a constrained regression approach under which we would have estimated the adult risk adjustment model using only the age-sex variables. Under this approach, we would have then re-estimated the model using the full set of HCCs, while constraining the value of the age-sex coefficients to be the same as those from the first estimation. We also considered creating separate models for enrollees with and without HCCs to derive two separate sets of age-sex coefficients. We evaluated the effect of these possible modifications, and ultimately decided to not move forward with such changes due to concerns of significantly undercompensating plans with higher-than-average actuarial risk.[45]

We continue to evaluate ways to improve the risk prediction of the HHS risk adjustment models under various approaches to model estimation that might more precisely account for the non-linearities in plan liability as referenced in the 2016 Risk Adjustment White Paper.[46] We are continuing to investigate HCC count models whereby the number of an enrollee's HCCs would be considered in calculating an enrollee's risk score, similar to the proposed Medicare Advantage risk adjustment model incorporating HCC counts.[47] As another alternative, we are evaluating whether a non-linear term might improve the prediction of the models over the current linear model specification method for the adult models. For example, this non-linear method would include an additive term that is the sum of the risk score exponentiated to a factor solved by the models. The added non-linear term would be a measure of overall disease burden in which having combinations of HCCs can have a larger effect than the sum of the individual HCCs.

We continue to evaluate alternative modeling approaches while considering several important trade-offs between making improvements to risk prediction and the year-to-year predictability of the models. We also are examining any shortcomings of the potential alternatives that include additional complexity, lack of transparency, and potential upcoding incentives. For example, because issuers would receive an incremental additional factor for coding another HCC, there might be an incentive for upcoding, particularly with a count model. We believe that these alternative approaches require further investigation prior to making any of these types of changes to the models. For these reasons, we intend to solicit comments in the future on potential proposed improvements to the current models, as well as alternative modeling methods involving either non-linear or count models for potential use in future benefit years of HHS-operated

[39] 81 FR 94099.

[40] If a plan is a low-cost plan with low claims costs, it could be an indication of mispricing, as the issuer should be pricing for average risk.

[41] See 81 FR 94080.

[42] See 81 FR at 94071 and 94074.

[43] See 83 FR at 93425.

[44] 81 FR 61455 at 61473.

[45] 81 FR at 94083.

[46] Available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[47] Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS–HCC Risk Adjustment Model. December 20, 2018. *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part1.pdf.*

risk adjustment model recalibration. We would especially be interested in comments regarding the factors HHS should consider in evaluating performance and their effects on subgroups in the population. We intend to also seek comment on the trade-offs we should consider, along with other risk adjustment topics.

Comment: One commenter requested that HHS reopen rulemaking proceedings, reconsider, and revise the Payment Notices for the 2017, 2018, and 2019 benefit years regarding the risk adjustment program under section 553(e) of the Administrative Procedure Act.

Response: The requests related to the 2017, 2018, and 2019 benefit year rulemakings are outside the scope of the proposed rule and this final rule, which is limited to the 2020 benefit year.

i. State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology, which is calibrated on a national dataset, for the state's individual, small group, or merged markets, by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s). We finalized that any requests received will be published in the respective benefit year's proposed notice of benefit and payment parameters, and the supporting evidence for the request will be made available for public comment.[48]

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation below).

We proposed to amend § 153.320(d)(3) to add language to provide that if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will do so, making available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information. Similar to the rate review program established under section 2794 of the PHS Act, HHS would release only information that is not a trade secret or confidential commercial or financial information as defined under the HHS FOIA regulations.[49] In these circumstances, similar to the federal rate review requirements, we proposed that any states requesting a reduction provide a version for public release that redacts the trade secret and confidential commercial or financial information as defined under the HHS FOIA regulations, while also providing an unredacted version to HHS for its review of the state's reduction request. We also proposed that state requests for individual market risk adjustment transfer reductions would be applied to both the catastrophic and non-catastrophic individual market risk pools, unless state regulators request otherwise.

We are finalizing our amendment to § 153.320(d)(3) to add language to provide that if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at 45 CFR 5.31(d), HHS will make available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. In light of comments received, we are not finalizing our proposal to apply requests for individual market risk adjustment transfer reductions to both the catastrophic and non-catastrophic individual market risk pools within the state, unless the state requested otherwise.

For the 2020 benefit year, HHS received a request to reduce risk adjustment transfers for the Alabama small group market by 50 percent. Alabama's request states that the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2020 benefit year will not exceed 1 percent, the *de minimis* premium increase threshold. We sought comment on Alabama's request to reduce risk adjustment transfers in the small group market by 50 percent for the 2020 benefit year. The request and additional documentation submitted by Alabama was posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html*. In light of our analysis of the information submitted with Alabama's request and the comments received, we are approving Alabama's request to reduce risk adjustment transfers in the small group market for the 2020 benefit year by 50 percent.

The following is a summary of the public comments we received on our proposals regarding state flexibility requests under § 153.320(d), and on Alabama's 2020 benefit year reduction request.

Comment: Commenters supported the ability of states to provide redacted versions of public-facing documents, although two raised questions about the scope of the redactions and whether the resulting documents would be sufficient to permit an effective review by interested parties.

Response: We are finalizing this amendment as proposed, as we believe it is important to protect information that contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at § 5.31(d). However, we will seek to implement an approach with targeted redactions focused on information that would be considered trade secrets or confidential commercial, or financial information under § 5.31(d), to support effective review by interested parties.

Comment: One commenter opposed the application of state individual market risk adjustment transfer reduction requests to both the individual market catastrophic and non-catastrophic risk pools within the state. The commenter noted that the individual market catastrophic and non-catastrophic risk pools have different characteristics that impact the size of transfers.

Response: After consideration of the commenters' concerns, we are not finalizing the proposed default to extend a state individual market reduction request to adjust transfers in both the individual catastrophic and non-catastrophic risk pools, unless the

[48] 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and § 153.320(d)(3).

[49] See § 154.215(h)(2).

state regulators request otherwise. When a state submits a reduction request related to the individual market transfers under the HHS state payment transfer formula, it will need to outline the risk pools the request and analysis apply to as part of its submission under § 153.320(d)(1). We are amending the regulatory language at § 153.320(d) to specifically reference state market risk pools consistent with this approach and to make some technical edits.

Comment: The majority of comments about Alabama's state flexibility request expressed support for the state's request, with many stating that states are best equipped to evaluate the needs of their insurance markets. Commenters opposing this request pointed to the fact that states can elect to operate the PPACA risk adjustment program and propose their own risk adjustment methodology, or that the current HHS-operated risk adjustment methodology is operating as intended. Multiple commenters expressed concern regarding the methodology Alabama used to provide evidence supporting its request, each stating that a more thorough actuarial analysis was needed, and some pointed to the requested 50 percent reduction as a crude and blunt figure not based on data.

Response: We agree that states are best equipped to understand the needs of their insurance markets and in the 2019 Payment Notice, HHS provided the flexibility for these reduction requests when a state elects not to operate the PPACA risk adjustment program. For some states, an adjustment to transfers calculated by HHS under the state payment transfer formula may more precisely account for cost differences attributable to adverse selection in the respective state market risk pools. Further, allowing these adjustments can account for the effect of state-specific rules or unique market dynamics that may not be captured in the HHS methodology, which is calibrated on a national dataset, without the necessity for states to undertake the burden and cost of operating their own PPACA risk adjustment program.

We reviewed Alabama's supporting evidence regarding the state's unique small group market dynamics that it believes warrant an adjustment to the HHS calculated risk adjustment small group market transfers for the 2020 benefit year. Alabama provided information demonstrating the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment transfer methodology from working as precisely as it would with a more balanced distribution of market share. Alabama state regulators noted they do not assert that the HHS formula is flawed, only that it results in imprecise results in the state's small group market that could further reduce competition and increase costs for consumers. The state regulators also provided information demonstrating that the request would have a *de minimis* impact on necessary premium increase for payment issuers, consistent with § 153.320(d)(1)(iii). We note that HHS reviewed the unredacted state supporting analysis in evaluating Alabama's request, along with other data available to HHS. We found the supporting analysis submitted by Alabama to be sufficient in evaluating the market-specific circumstances validating Alabama's request.

Based on our review, we agree that any necessary premium increase for issuers likely to receive payments as a result of a 50 percent reduction to risk adjustment transfers in the Alabama small group market for the 2020 benefit year would not exceed 1 percent. HHS has determined that the state has demonstrated the existence of relevant state-specific factors that warrant an adjustment to more precisely account for relative risk differences and that the adjustment would have a *de minimis* effect. Therefore, we are approving Alabama's requested reduction under § 153.320(d)(4)(i)(B) based on the state regulators' identification of unique state-specific factors in the Alabama small group market and the supporting analysis of a *de minimis* effect of the reduction requested. The 50 percent reduction will be applied to the 2020 benefit year plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation below) for the Alabama small group market.

We also note that state regulators seeking a reduction to risk adjustment transfers in the state's individual catastrophic risk pool, individual non-catastrophic risk pool, small group market or a merged market for the 2021 benefit year should submit supporting materials to HHS as established under § 153.320(d). We will review any requests received on an annual basis, will make the supporting evidence publicly available for comment in the proposed notice of benefit and payment parameters for the respective benefit year, and will consider the relevant comments in our review of the state request for the applicable benefit year.

ii. The Risk Adjustment Transfer Methodology

Although the proposed HHS risk adjustment transfer methodology for the 2020 benefit year is unchanged from what was finalized in the 2019 Payment Notice (83 FR 16954 through 16961), we believe it is useful to republish the calculation in its entirety. Additionally, we are republishing the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although these factors and terms also remain unchanged in this final rule.[50] Transfers (payments and charges) under the state payment transfer formula will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The state payment transfer calculation that is part of the HHS risk adjustment transfer methodology is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)}\right] \bar{P}_s$$

Where:

$\bar{P}_S$ = Statewide average premium;
$PLRS_i$ = plan *i*'s plan liability risk score;
AV_i = plan *i*'s metal level AV;
ARF_i = allowable rating factor;
IDF_i = plan *i*'s induced demand factor;
GCF_i = plan *i*'s geographic cost factor;
s_i = plan *i*'s share of state enrollment.

The denominator will be summed across all risk adjustment covered plans in the risk pool in the market in the state.

The difference between the two premium estimates in the state payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The value of the plan average risk score by itself does not determine whether a plan will be assessed a charge or receive a payment—even if its risk score is greater than 1.0, it is possible that the plan will be assessed a charge if the premium

[50] See 83 FR 16930 at 16960.

compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the state market risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.[51] This resulting PMPM plan payment or charge will be multiplied by the number of billable member months to determine the plan's payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state.

We defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of plan i (P_i) multiplied by plan i's share of statewide enrollment in the market risk pool (s_i). The statewide average premium will be adjusted to remove a portion of the administrative costs that do not vary with claims (14 percent) as follows:

$$\bar{P}_S = (\Sigma_i(s_i \cdot P_i)) * (1 - 0.14) = (\Sigma_i(s_i \cdot P_i)) * 0.86$$

Where:

s_i = plan *i*'s share of statewide enrollment in the market in the risk pool;

P_i = average premium per member month of plan *i*.

The high-cost risk pool adjustment amount will be added to the state payment transfer formula to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable; and (2) the charge term, representing a percentage of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool *m* (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (TP_i). For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amount.

The total plan transfers for a given benefit year will be calculated as the product of the plan PMPM's transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment transfer methodology for a benefit year will be calculated as follows:

$$Total\ transfer_i = (T_i \cdot M_i) + (HRP_i - (HRPC_m \cdot TP_i)$$

Where:

$Total\ Transfer_i$ = Plan *i*'s total HHS risk adjustment program transfer amount;

T_i = Plan *i*'s PMPM transfer amount based on the state transfer calculation;

M_i = Plan *i*'s billable member months;

HRP_i = Plan i's total high-cost risk pool payment;

$HRPC_m$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool *m*;

TP_i = Plan *i*'s total premium amounts.

As we noted above, we approved Alabama's small group market reduction request for the 2020 benefit year. The approved reduction percentage (50 percent) will be applied to the 2020 benefit year plan PMPM payment or charge transfer amount (T_i) under the state payment transfer calculation for the Alabama small group market risk pool. The Alabama reduction to the PMPM transfer amounts is not shown in the HHS risk adjustment state payment transfer formula above. While we note that we addressed comments regarding the high-cost risk pool transfer calculation in the high-cost risk pool section above and comments regarding the cost-scaling factor in the state payment transfer formula in the overview of the transfer methodology section above, the following is a summary of the other public comments we received on the total plan transfer calculation published in the proposed rule.

Comment: One commenter supported HHS reducing the statewide average premium to account for costs associated with administrative expenses that do not vary with claims. Another commenter recommended that HHS publish the analysis used to determine the 14 percent administrative expense factor, including the specific line items from the Medical Loss Ratio (MLR) Annual Reporting Form that were included as administrative expenses that do not vary with claims to determine the 14 percent reduction of premium.

Response: As detailed in the 2018 Payment Notice,[52] to derive this parameter, we analyzed and categorized administrative and other non-claims expenses in the MLR Annual Reporting Form,[53] and estimated, by category, the extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, netting out claims costs financed through cost-sharing reduction payments.[54] We compared these expenses to total costs, rather than directly to premiums, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data are available. Using this methodology, we determined that the mean administrative cost percentage is 14 percent. While we are assessing whether other data sources might be able to supplement this analysis for potential updates for future years, we continue to believe that the current percentage represents a reasonable percentage of administrative costs on which risk adjustment transfers should not be calculated.

c. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.710)

In the 2018 Payment Notice,[55] we finalized the collection of masked enrollee-level data from issuers' EDGE servers (referred to as ''enrollee-level EDGE data'') beginning with the 2016 benefit year to recalibrate the HHS risk adjustment models and inform development of the AV Calculator and methodology.

In the 2018 Payment Notice, we also stated that we would consider using this enrollee-level EDGE data in the future to calibrate other HHS programs in the individual and small group markets, and to produce a public use file to help governmental entities and independent researchers better understand these markets. We noted that a public use file derived from these data would be de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, would not include proprietary issuer or plan identifying data, and would adhere to HHS rules and policies regarding protected health information (PHI) and personally identifiable information (PII). We also described in guidance the data elements in the enrollee-level EDGE data set and

[51] As detailed elsewhere in this final rule, catastrophic plans and non-catastrophic plans and merged market plans are considered part of the individual market for purposes of the national high-cost risk pool payment and charge calculations.

[52] 81 FR 94100.

[53] To estimate the administrative cost parameter, we used information in the MLR Annual Reporting Form on health care quality improvement expenses incurred, the federal and state taxes and licensing on regulatory fees, and other non-claims costs. We also assumed 25 percent of general administrative expenses, as reported on the MLR Annual Reporting Form would be included in the administrative cost parameter. Information on the medical loss ratio data are available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[54] The analysis used 2016 CSR payment data.

[55] See 81 FR 94058 at 94101.

the data elements proposed to be made available for research requests.[56]

Under the HIPAA safe harbor for de-identification of data at 45 CFR 164.514(b)(2), public use files are considered de-identified if they exclude 18 specific identifiers that could be used alone or in combination with other information to identify an individual who is a subject of the information. To make the enrollee-level EDGE data available as a public use file that comports with the requirements of § 164.514(b)(2), we would have to remove dates (other than the year) and ages for enrollees ages 90 or older,[57] and determine that the information could not be used alone or in combination with other information to identify an individual who is a subject of the information. Commenters stated that a public use file would be limited in its usefulness because it excludes dates that would be useful to conduct health services research. A limited data set, as defined at § 164.514(e)(2), may include dates, which could enable requestors to do analyses they would not be able to do with a public use file. In addition, under § 164.514(e)(4), a limited data set recipient must enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information. We believe entities seeking to use the enrollee-level EDGE data will be able to better understand the individual and small group markets with a limited data set.

Thus, in the proposed rule, we proposed to create and make available by request a limited data set file rather than a public use file, as we believe a limited data set file will be more useful to requestors for research, public health, or health care operations purposes. We noted that, under this proposal, we would make enrollee-level EDGE data, beginning with the 2016 benefit year, available as a ''limited data set'' file under § 164.514(e). This limited data set file would not include the direct identifiers of the individual or of relatives, employers, or household members of the individual, which are required to be removed under the limited data set definition at § 164.514(e)(2) and which issuers do not submit to their EDGE servers. We also proposed to limit disclosures of the limited data set to requestors who seek these data for research, public health, or health care operations purposes, as those terms are defined under § 164.501. We stated that we would require qualified requestors to sign a data use agreement to ensure these data will be maintained, used, and disclosed only as permitted under the HIPAA Privacy Rule, and to ensure that any inappropriate uses or disclosures are reported to HHS. We noted that HHS components would also be able to request the limited data set file for research, public health, or health care operations purposes, as those terms are defined under § 164.501. We also clarified that, if the proposal is finalized, we would make a limited data set file available on an annual basis, reflecting enrollee-level data from the most recent benefit year available on EDGE servers. We stated that if we finalize the proposal to make a limited data set file available, HHS would not offer a public use file based on the enrollee-level EDGE data. We sought comment on this proposal.

In addition, we explained in the proposed rule that we received feedback in response to the guidance describing the data elements to be made available as part of the public use file for research requests [58] noting that researchers would benefit from additional data elements on enrollees' geographic identifiers, enrollees' income level, provider identifier, provider's geographic location, hashed claim identifier, enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment). We noted that we began collecting a claim identifier [59] to associate all services rendered under the same claim beginning with the 2017 benefit year enrollee-level EDGE data. Therefore, we stated that if we were to finalize the limited data set proposal, we would be able to include this grouped claims identifier beginning for the 2017 benefit year enrollee-level EDGE limited data set file. However, regarding the other data elements commenters requested, we explained that either issuers do not submit them to their EDGE servers, or we currently do not extract them from issuers' EDGE servers due to concerns about the ability to use the data element(s) to identify issuers or plans. For example, issuers do not currently submit data to their EDGE servers on enrollees' plan benefit design, specific cost-sharing elements (deductibles, copayments), provider identifiers, providers' geographic location, enrollees' income level, or enrollees' geographic location more specific than the rating area, and therefore, we are unable to extract such information as part of the enrollee-level EDGE data. However, issuers do submit enrollees' state and rating areas as part of the EDGE server submissions, making it possible to extract these data elements from the issuers' EDGE servers as part of the enrollee-level EDGE data. We stated in the proposed rule that, if we were to extract state and rating area data elements, we could also make such information available as part of the proposed enrollee-level EDGE limited data set file. We stated in the proposed rule that we continue to believe the enrollee-level EDGE data can increase cost transparency for consumers and stakeholders for the individual and small group markets, and can be a useful resource for government entities and independent researchers to better understand these markets. We also recognized access and use of enrollee-level EDGE data should continue to safeguard enrollees' privacy and security and issuers' proprietary information. We reiterated that we use the enrollee-level EDGE data to recalibrate the HHS risk adjustment models and inform development of the AV Calculator and methodology and stated that extracting additional state and rating area information could enable HHS to assess the impact of differences in geographic factors in the HHS risk adjustment methodology. In addition, we stated that stakeholders have noted that adding geographic elements to the AV Calculator would better estimate the AV of plans based on the cost differences across regions. Extraction of these geographic details (state and rating area) from issuers' EDGE servers could also help support other HHS programs and policy priorities, as well as provide additional data elements for researchers. We noted that although these geographic data elements are not currently extracted from the enrollee-level EDGE data set, extracting them would not increase burden for issuers, as issuers already submit these data elements as part of the EDGE server data submission process. We stated in the proposed rule that if we were to extract state and rating area

[56] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf.*

[57] HHS does not currently collect any of the other data elements under § 164.514(b)(2) that would require de-identification.

[58] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf.*

[59] For the 2017 benefit year, we have included a unique claim identifier field, a hashed claim identifier, in the data extract. The claim identifier is a random hashed number assigned for each set of service line items associated with each claim, and cannot be used to identify the enrollee, plan or medical record. Including this claim identifier will allow data users to associate all service line items rendered under the same claim and also permit more rigorous checks of data quality.

information, we would do so as part of the enrollee-level EDGE data extraction and would use this information to support the recalibration and policy development related to the HHS-operated risk adjustment program, the AV Calculator and methodology, as well as other HHS programs in the individual and small group (including merged) markets. We sought comment on whether to extract state and rating area information for enrollees as part of the enrollee-level EDGE data. We also sought comment on how state and rating area information could be used in the HHS-operated risk adjustment program, AV Calculator and methodology, and other HHS programs in the individual and small group (including merged) markets, as well as on how these data elements could benefit researchers and public health. We sought comment on, if we were to extract these data elements, whether to make state and rating area information available as part of the proposed limited data set file that would be made available to qualified requestors. We sought comment on the advantages and disadvantages of using state and rating area information for recalibration of the HHS-operated risk adjustment program, the AV Calculator and methodology, and other HHS individual and small group (including merged) market programs. In addition, we sought specific comment on possible research purposes for these data elements, whether the benefits of extracting these additional data elements outweigh the potential risk to issuers' proprietary information, and whether extraction of these data elements is consistent with the goals of a distributed data environment.

We also sought specific comment on the other data elements outlined in the proposed rule that commenters requested be part of the enrollee-level EDGE dataset, but that issuers do not currently submit to their EDGE servers (for example, enrollees' income level, provider identifier, provider's geographic location, hashed claim identifier,[60] enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type, such as deductible, coinsurance, and copayment), and other enrollment and claims data elements not otherwise described in the proposed rule, and whether collection of such data elements could benefit the calibration of the HHS risk adjustment program, the AV calculator and methodology, and other HHS individual and small group (including merged) market programs. We also sought specific comment with examples on whether other data elements that issuers do not currently submit to their EDGE servers could benefit further research, public health, or health care operations as part of a limited data set file made available to qualified requestors.

Finally, we proposed to extend the use of enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs (for example, the HHS-operated risk adjustment program, the AV calculator and methodology, and the out-of-pocket calculator), as well as to conduct policy analysis for the individual and small group (including merged) markets (for example, to assess the market impacts of policy options being deliberated). We explained that we believe these additional uses of the enrollee-level EDGE data would enhance our ability to develop and set policy for the individual and small group (including merged) markets and avoid burdensome data collections from issuers.

To further our commitment to increasing transparency in health care markets and help the public better understand these markets, we are finalizing our proposal with one modification. Under our final policy, we will create and make available, on an annual basis, enrollee-level EDGE data as a limited data set file for qualified requestors who seek these data for research purposes. We will not make this limited data set available to requestors for public health or health care operations activities. While these purposes are permitted by the HIPAA Privacy Rule, in light of comments received and HHS' operational limitations, HHS will not make this limited data set file available to requestors for public health or health care operations activities at this time. We note that we may consider exploring the use of the public health and heath care operations pathways for making the limited data set file available in the future. We did not propose to extract state and rating area information from issuers' EDGE servers or collect additional data elements, and based on comments received, at this time, we do not believe the benefits from additional data element extractions or collections would outweigh the costs of potential increased risk to issuers' proprietary information and increased issuer burden. As noted in the proposed rule, we will include the grouped claims identifier beginning with the 2017 benefit year enrollee-level EDGE limited data set file, as that is the first year that data element is available. We are finalizing our proposal to allow HHS to use the enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs, including to conduct recalibration of the HHS risk adjustment program and to make updates to the AV Calculator, and to conduct policy analysis for the individual and small group (including merged) markets. We believe these additional uses of the enrollee-level EDGE data and reports will enhance our ability to develop and set policy for the individual and small group (including merged) markets and avoid burdensome data collections from issuers. We clarify that our policies regarding HHS uses of the enrollee-level EDGE data apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. As we stated in the proposed rule, other HHS components will be able to request the EDGE limited data set file for research purposes, as that term is defined under § 164.501. We also note that the enrollee-level EDGE data may be subject to disclosure as otherwise required by law.[61]

Comment: Many commenters supported HHS' proposal to create and make available by request a limited data set file using enrollee-level EDGE data. These commenters noted that the limited data set file will support research, public health, external accountability, and transparency. One commenter stated these data will provide researchers with a better understanding of Exchange functions and enrollees' health needs. Another commenter noted these data will help support state departments of insurance in the rate review process. However, numerous other commenters did not support the proposal to offer a limited data set file. Most of these commenters expressed concerns about the potential for unauthorized disclosure of PII and issuer proprietary information. One commenter stated it was particularly concerned with the enrollee-level EDGE data being used for the purpose of health care operations. One commenter stated HHS has not provided adequate assurances that the information would not be used for unauthorized purposes.

[60] As noted previously, we began extracting a hashed claim identifier to identify all the service line items that belong to the same claim beginning with the 2017 benefit year enrollee-level EDGE extract.

[61] See, for example, 2 U.S.C. 601(d).

Several commenters expressed concerns about the potential of these data to undermine provider contracting and rate negotiations. Some commenters noted that offering these data could erode issuer confidence and could be used by some issuers to competitively price products and game the federal risk adjustment program.

Response: We appreciate the comments we received on our proposal to create and make available by request a limited data set file using the enrollee-level EDGE data. We continue to believe the enrollee-level EDGE data can increase cost transparency for consumers and stakeholders for the individual and small group (including merged) markets and can be a useful resource for government entities and independent researchers to better understand these markets. These benefits align with HHS' goal to promote increased transparency in health insurance markets. We also recognize that any access to and use of the enrollee-level EDGE data should continue to safeguard enrollee privacy and security and issuers' proprietary information. While we acknowledge and appreciate commenters' concerns, we believe the benefits of making these data available for research purposes outweigh the potential risks associated with unauthorized disclosure of these data. While some commenters stated that the limited data set file will benefit public health, others expressed concern. Moreover, HHS does not currently make limited data sets available for health care operations or public health purposes. Therefore, as discussed above, in light of comments received and HHS' operational limitations, HHS will not make this limited data set file available to requestors for public health or health care operations activities at this time. We note that we intend to use the existing process to make limited data set files available and requestors will be required to provide a research purpose as part of their requests.[62] We believe the potential risks will be mitigated through the existing controls that limit access to these data to qualified requestors who seek these data for research purposes, by requiring requestors to enter into a data use agreement, and by continuing to apply the precautions already in place to mask enrollee identifiers. Under § 153.720, issuers do not upload PII to their EDGE servers, and must establish and use a unique masked identification number for each enrollee and may not include the enrollee's PII in the masked enrollee identification number. Furthermore, when HHS extracts enrollee-level EDGE data, we create a hashed enrollee identifier, a system-generated random number, that cannot be linked back to the issuers' EDGE servers to identify the issuer or plan. As we noted in the proposed rule and reiterated above, this limited data set file will not include the direct identifiers of the individual or of relatives, employers, or household members of the individual, which are required to be removed under the limited data set definition at § 164.514(e)(2), as issuers do not upload these identifiers to their EDGE servers. Thus, we believe we will continue to protect enrollees' PII and issuers' proprietary information. Furthermore, the limited data set regulations under § 164.514(e) impose specific limitations on use and disclosure of these types of data, and qualified requestors will be required to abide by these requirements and our policies for limited data sets. Requestors will be required to provide a research purpose as part of their request. The data use agreement will require the requestors to maintain, use, and disclose the limited data set only as permitted under § 164.514(e) and report any inappropriate uses or disclosures of these data.[63] As discussed below, we are not finalizing a policy to extract state and rating area information from issuers' EDGE servers, and therefore, we will not include those data in the limited data set file developed using enrollee-level EDGE data. Because the limited data set files will not include issuer or plan identifiable information, requestors with access to the limited data set files will not receive or be able to misuse any issuer trade secret information. Additionally, the extracted enrollee-level EDGE data does not include premium information from issuers' EDGE servers and therefore requestors will not be able to determine issuer-specific rate negotiation information. Furthermore, issuers do not upload provider (for example, hospital or physician) identifying information to their EDGE servers. Therefore, these types of provider identifiers cannot be extracted for the enrollee-level EDGE data collection either, mitigating commenters' concerns that the data could reveal issuer-specific provider contracting or negotiated price information. Therefore, we do not believe the enrollee-level EDGE data could be used to identify issuer-specific proprietary pricing data.

Comment: One commenter sought clarity on the types of entities that can request the limited data set file and the process HHS will use to consider requests. Another commenter noted HHS should develop strict standards for release of these data as a limited data set for which it should seek public comment.

Response: As described in this rule, the limited data set will be made available in accordance with the regulations at § 164.514(e) and existing policies and procedures for limited data set requests. The limited data set file, when available, would be provided to qualified requestors who seek these data for research purposes, consistent with other limited data sets made available by CMS.[64] Requestors will need to submit a research purpose statement and sign a data use agreement to ensure these data will be used for the stated purpose only and that these data will be maintained, used, and disclosed only as permitted by the agreement or otherwise required by law. We will have final discretion over the decision whether to approve a request for access to the limited data set file.

Comment: Several commenters expressed concern with any use of state and rating area information to support the operation of the risk adjustment program and other HHS programs. Some commenters noted outside entities could identify issuers and, possibly, individual enrollees in a limited data set if it included state and rating area data elements, which could risk issuers' proprietary information and enrollees' PII. However, some commenters who supported release of a limited data set also supported including state and rating area information in the limited data set, stating that this information would make these data more useful to researchers. Most commenters did not support the use of state and rating area information to calibrate the AV Calculator. Most commenters noted this would add increased complexity with little benefit, cause consumer and issuer confusion, and result in unintended consequences affecting the underlying AV Calculator and methodology. One commenter stated that there may not be adequate data in some states and rating areas to build models for the AV Calculator and methodology.

Response: We appreciate the comments we received regarding

[62] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.*

[63] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.*

[64] For information on the CMS limited data set process and data use agreements, see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html#Policies.*

extraction and use of state and rating area information from issuers' EDGE servers. While we believe state and rating area information would enhance the usefulness of the enrollee-level EDGE data, including for the limited data set file, we agree that the risk of potential unauthorized disclosure of issuer- or plan-level information through inclusion of geographic identifiers outweighs these benefits. We understand that including geographic identifiers in the limited data set would enable qualified requestors who receive the limited data set file to identify issuers in states or rating areas with only one issuer. We appreciate the comments describing concerns regarding the extraction of state and rating area data elements, and as we did not propose to extract and use those data elements for the enrollee-level EDGE data, we are not making any changes in that regard at this time.

We agree with commenters that using geographic information for the AV Calculator and methodology is neither required nor would enhance the current methodology. For AV Calculator and methodology updates in future years, we will continue to use enrollee-level EDGE data in its current format (without the state or rating area information).

Comment: Many commenters did not support the collection of additional data elements, such as enrollees' income level, provider identifier, plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment), that issuers are not already submitting to their EDGE servers. Commenters stated the submission of additional data elements would be administratively complex, burdensome, and beyond the minimum necessary data elements needed for recalibration of the risk adjustment program. One commenter noted HHS should expand the data elements available in the limited data set file, but did not provide further specificity, including how HHS would do that without first collecting those data elements on the issuers' EDGE servers.

Response: We believe that collection of additional data elements that are not currently submitted by issuers to their EDGE servers, such as enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment), would enhance the usefulness of the enrollee-level EDGE data, including for the limited data set. However, we acknowledge the commenters' concerns that collection of additional data elements on issuers' EDGE servers could be administratively complex and burdensome for issuers, as it would increase their data collection requirement, and for HHS, as these data elements would have to be validated and added to the file structure that is submitted through the distributed data environment. We recognize the need to balance the benefits of enhanced transparency and helping the public better understand these markets against minimizing issuer and government costs and burden. As we did not propose to make any changes in this regard, we are not making any such changes at this time, and will consider whether to propose collection of any additional data elements for the EDGE server submissions for future benefit years.

Comment: Some commenters supported HHS broadening its uses of enrollee-level EDGE data to improve and administer programs within HHS' scope, including to recalibrate the risk adjustment program and the AV Calculator and methodology. Most who commented supported HHS broadening the use of the enrollee-level EDGE data as proposed. One commenter noted HHS should not use these data for any other purpose without express issuer permission. Some commenters noted HHS should not use EDGE server data outside of the risk adjustment program, stating that such use would be inconsistent with the intent of using a distributed data environment for administering the risk adjustment program. One commenter did not support the use of EDGE data for policy analysis outside of the risk adjustment program, and recommended that, if HHS proceeds with this proposal, it should define policy analysis and seek public comment.

Response: We are finalizing our proposal to allow HHS to use the enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs (for example, the HHS-operated risk adjustment program, the AV Calculator and methodology and the out-of-pocket calculator), as well as to conduct policy analysis for the individual and small group (including merged) markets. We agree with commenters that our use of the enrollee-level EDGE data for these purposes will help improve our understanding of the nuances unique to the individual and small group (including merged) markets so that we can be responsive to market fluctuations and pursue updates to these programs, as appropriate. Additionally, we anticipate that leveraging these data in this way will increase efficiencies by reducing our need to initiate new, potentially burdensome data collections.

HHS may use the enrollee-level EDGE data to help inform which of various policies related to the individual and small group (including merged) markets will further HHS' goals to promote transparency, support innovation in the private sector, reduce burden on stakeholders, and improve program integrity. Generally, policies that could be informed by these data would be developed or revised through the notice-and-comment rulemaking process. We do not believe using the enrollee-level EDGE data and reports extracted from issuers' EDGE servers for the purposes we have outlined is inconsistent with the intent of using a distributed data environment for the HHS operated risk adjustment program. In the 2014 payment notice, we finalized the distributed data model for data collection for the risk adjustment and reinsurance programs when HHS operates those programs on behalf of a State.[65] In evaluating data collection options, we determined the distributed data collection model proved the most effective approach for obtaining and processing the data necessary for both reinsurance and risk adjustment calculations because such a model would minimize issuer burden while protecting enrollees' privacy. We did not propose and are not making any changes to the risk adjustment data transfer process between issuers and HHS. As discussed previously, we recognize the sensitivity of enrollee-level EDGE data and are taking precautions to safeguard these data. We believe the analyses and uses described in this rule would benefit issuers and the broader individual and small group market (including merged market) stakeholders. While we do not believe issuer permission is necessary for HHS to use enrollee-level EDGE data or reports as HHS would not make issuer proprietary information public nor would HHS require issuers to submit additional data elements, we appreciate the sensitivities related to enrollee-level EDGE data and intend to continue following the current process, under which we engage in notice-and-comment rulemaking prior to expanding uses or disclosures of this data.

d. Risk Adjustment Default Charge (§ 153.740(b))

As described below, we are finalizing a change to the timeline for publication of the 2017 benefit year risk adjustment data validation results and the

[65] 2014 Payment Notice, 78 FR 15497.

accompanying collection and payment of adjustments related to these results. Consistent with those changes, the 2018 benefit year summary risk adjustment transfer report issued by June 30, 2019, will not reflect the impact of the 2017 benefit year risk adjustment data validation adjustments on 2018 risk adjustment transfers, but will continue to include information on the assessment and allocation of the applicable benefit year's risk adjustment default charges under § 153.740(b). HHS' calculation of the 2018 benefit year PMPM risk adjustment default charge will be equal to the 90th percentile of the 2018 risk adjustment transfers not adjusted with the results of 2017 risk adjustment data validation.[66]

e. Risk Adjustment User Fee for 2020 Benefit Year (§ 153.610(f))

As noted in this rule, if a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate a risk adjustment program on its behalf. For the 2020 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice,[67] HHS' operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25R established federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A–25R to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2019 Payment Notice,[68] we calculated the federal administrative expenses of operating the risk adjustment program for the 2019 benefit year to result in a risk adjustment user fee rate of $1.80 per billable member per year or $0.15 PMPM, based on our estimated contract costs for risk adjustment operations, estimates of billable member months for individuals enrolled in risk adjustment covered plans, and eligible administrative and personnel costs related to the administration of the HHS-operated risk adjustment program. For the 2020 benefit year, we proposed to generally use the same methodology to estimate our administrative expenses to operate the program, with the modifications described in this rule. These costs cover development of the risk adjustment models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment activities related to the HHS-operated program. To calculate the user fee, we divided HHS' projected total costs for administering the risk adjustment program by the expected number of billable member months in risk adjustment covered plans in the 50 states and the District of Columbia where HHS will operate risk adjustment for the 2020 benefit year.

We estimated the total cost for HHS to operate the risk adjustment program for the 2020 benefit year to be approximately $50 million, and the risk adjustment user fee would be $2.16 per billable member per year, or $0.18 PMPM. The updated cost estimates attribute all costs related to the EDGE server data collection and data evaluation (quantity and quality evaluations) activities to the risk adjustment program rather than sharing them with the reinsurance program, which is no longer operational.[69] We collected amounts under the reinsurance program for administrative expenses related to that program, which partially funded contracts that were used for both the risk adjustment and reinsurance programs. We no longer allocate indirect costs for personnel or administrative costs to the reinsurance program, and are reflecting the full value of those costs as part of risk adjustment operations for the 2020 benefit year. The risk adjustment user fee costs are also estimated to be slightly higher due to increased contract costs based on additional activities for the risk adjustment data validation program development and execution, including updated cost estimates associated with the non-pilot years of the risk adjustment data validation program, including estimates for error rate adjustments, development of the new risk adjustment data validation audit tool, and additional contractor support for risk adjustment data validation discrepancies and appeals. The estimated costs also incorporate the full personnel and administrative costs associated with risk adjustment program development and operations in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fee for the 2019 Payment Notice final rule incorporated only a portion of the personnel costs, and excluded indirect costs. The 2020 benefit year risk adjustment user fee includes the full amount for eligible personnel costs, as well as eligible indirect costs. Finally, we estimated individual and small group market billable member months for the 2020 benefit year to remain roughly the same, as observed in the most recent risk adjustment data available for the 2017 benefit year.

We received one comment on the proposed risk adjustment user fee for the 2020 benefit year, which supported our proposal to establish a risk adjustment user fee for the 2020 benefit year of $2.16 per billable member per year, or $0.18 PMPM. We are finalizing the risk adjustment user fee rate for the 2020 benefit year as proposed.

3. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

We conduct risk adjustment data validation under §§ 153.630 and 153.350 in any state where HHS is operating risk adjustment on the state's behalf, which for the 2020 benefit year is all 50 states and the District of Columbia. The purpose of risk adjustment data validation is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and

[66] As established in the 2015 Payment Notice at 79 FR 13790, a PMPM default charge is equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. See 79 FR at 13790. While this percentile was subsequently adjusted to the 90th percentile in the 2017 Payment Notice, the PMPM amount is otherwise calculated in the same manner. See 81 FR 12237.

[67] See 78 FR 15409 at 15416.

[68] 83 FR 16930 at 16972.

[69] Although the 2016 benefit year was the final benefit year for the reinsurance program, close-out activities continued in the 2018 fiscal year, including the collection of the second part of the 2016 benefit year contributions for contributing entities that elected the bifurcated schedule, which were due by November 15, 2017, and are expected to continue in the 2019 fiscal year.

proper functioning of the HHS-operated risk adjustment program. Risk adjustment data validation consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation auditor. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit. In the proposed rule, we set forth a number of proposed amendments and clarifications to the HHS risk adjustment data validation program in light of experience and feedback from issuers during the first 2 pilot years of the program.

The following is a summary of the general public comments we received related to risk adjustment data validation requirements when HHS operates risk adjustment. Additional comments related to the error estimation methodology and negative error outliers are discussed later in this rule.

Comment: A few commenters urged HHS to adopt the HEDIS (Healthcare Effectiveness Data and Information Set) audit methodology, which only requires medical record review for supplemental codes that the plan pulls from medical records.

Response: We continue to seek ways to improve the HHS risk adjustment data validation program for both accuracy and user experience, and will continue to examine approaches taken by other organizations when making updates to the risk adjustment data validation process. However, because the intent of risk adjustment data validation is to ensure the integrity of the risk adjustment program by validate all diagnoses for which an issuer received credit in risk adjustment, we believe that risk adjustment data validation should include all diagnoses, and not simply be limited to supplemental diagnoses. Additionally, we note that the HEDIS audit methodology is a two-part process that is customized based on an organization's informational systems, and that we believe that the distributed data environment precludes the need for such customization. As such, we are maintaining our current methodology for risk adjustment data validation.

Comment: A few commenters requested relief for issuers experiencing difficulty with obtaining medical records from providers in connection with the issuers' risk adjustment data validation. One commenter stated that it was having difficulty accessing medical records that included mental health or substance use disorder diagnoses because state privacy law was more stringent than the relevant federal requirements, and that enrollee consent must be obtained even for summary information. Another commenter requested that HHS create a process to exempt issuers from validating HCCs for which a provider refused to supply a medical record and the issuer demonstrated good faith in trying to obtain such record.

Response: In the 2019 Payment Notice, we finalized § 153.630(b)(6) to provide relief to issuers that are prohibited from obtaining medical records by state privacy laws in response to similar concerns expressed by some issuers. We recognize the difficulties that federal and state privacy laws can pose to issuers of risk adjustment covered plans for purposes of risk adjustment data validation, and our intention is not to penalize issuers that seek to obtain the necessary information from providers. We are continuing to consider possible approaches that permit users to meet the requirements of risk adjustment data validation consistent with all applicable privacy laws. Although we appreciate the comments, the proposed rule did not propose changes to § 153.630(b)(6), and we are not making any changes to that provision as part of this final rule.

a. Varying Initial Validation Audit Sample Size (§ 153.630(b))

In the 2014 Payment Notice, we established the risk adjustment data validation program that HHS uses when operating risk adjustment on behalf of a state. Consistent with § 153.350(a), HHS is required to ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that state. The current enrollee sample size selected for the initial validation audit is 200 enrollees statewide (that is, combining an issuer's individual, small group, and merged market enrollees (as applicable) in risk adjustment covered plans in the state) for each issuer's Health Insurance Oversight System (HIOS) ID, based on sample size precision analyses we conducted using proxy data from the Medicare Advantage program. Those analyses calculated a range of sample sizes to target a 10 percent precision at a 95 percent confidence level. The resulting range of sample sizes were between 100 and 300, and we selected 200 as a midpoint.[70] In the 2015 Payment Notice, we stated that, after the initial years of risk adjustment data validation, we would evaluate our sampling assumptions using actual enrollee data and consider using larger sample sizes for issuers that are larger or have higher variability in their enrollee risk score error rates, and smaller sample sizes for issuers that are smaller or have lower variability in their enrollee risk score error rates. We also stated that we would use our sampling experience in the initial years of risk adjustment data validation to evaluate using issuer-specific sample sizes.

The current initial validation audit sample size of 200 was selected to achieve an estimated 10 percent precision, assuming a distribution of risk score errors similar to that found in the Medicare Advantage risk adjustment data validation program. However, since the HCC group failure rate approach to error estimation (referred to as the HCC failure rate methodology) was implemented beginning with the 2017 benefit year of risk adjustment data validation, we anticipate that the calculated precision would differ from the estimate we used, which was based on the Medicare Advantage error rate data. Therefore, beginning with the 2019 benefit year of risk adjustment data validation,[71] we proposed to vary the initial validation audit sample size and set forth in detail and sought comment on several different approaches for varying the initial validation audit sample size. One proposed approach would vary the initial validation audit sample size based on issuer characteristics, such as issuer size, prior year HCC failure rates, and sample precision. We also solicited comment on an alternative approach to adjusting sample size that would increase sample sizes based on issuer size alone, and would continue to use the proxy Medicare Advantage risk score error rate data for the accompanying precision analyses. Additionally, we solicited comment on whether the issuers' enrollment should be calculated based on the year that is being adjusted or based on the benefit year in which the HCC failure occurred. In response to a comment we received on the 2019 Payment Notice that larger sample sizes could improve the accuracy of issuers' risk adjustment data validation samples, we solicited comment on whether to permit issuers of any size and HCC failure rate to request a larger sample

[70] See 79 FR 13743 at 13756.

[71] Activities related to the 2019 benefit year risk adjustment data validation generally begin in the second quarter of CY 2020.

size before the applicable benefit year's initial validation audit commences. Finally, we also explained that under these alternative approaches, HHS would not increase the sample above 200 enrollees when performing the second validation audit pairwise means test because a 200-enrollee sample is sufficient to achieve statistical significance in that test.

After consideration of the comments submitted, we are not finalizing any increase to the initial validation audit sample size at this time. We will continue to consider potential changes to initial validation audit sample sizes for future benefit years of risk adjustment data validation. We may revisit these proposals, and may also consider additional alternatives, following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results.

Comment: A number of commenters did not support varying the initial validation audit sample size at all (regardless of the approach to do so), and recommended that HHS maintain the current sample size of 200 enrollees. These commenters stated that increasing the initial validation audit sample size would create undue administrative and financial burdens, as well as disruption to plans and the provider community, without improving the quality of the data validation results. Other commenters generally supported varying the initial validation audit sample size, stating that larger sample sizes would help meet desired precision targets, and lend additional credibility to risk adjustment data validation results.

Response: We continue to believe that larger sample sizes would help achieve the goals of increasing initial validation audit sample precision and ensuring the statistical validity of the sample. However, in light of the comments regarding the potential uncertainty related to using 2017 benefit year risk adjustment data validation results to make such changes, we are not finalizing any changes to the initial validation audit sample size at this time. We are maintaining the current initial validation audit sample size of 200 enrollees for all issuers of risk adjustment covered plans required to participate in the HHS risk adjustment data validation program. We are also sensitive to the concerns about the potential increased burdens for stakeholders and will consider how best to strike the balance between mitigating these burdens and increasing precision as we continue to analyze different approaches for varying sample size. HHS intends to revisit potential changes to initial validation audit sample sizes for future benefit years following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results.

Comment: While one commenter supported the proposal to use 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year, another commenter did not support using 2017 risk adjustment data validation results, because the commenter believed that the methodology would not appropriately reflect the 2019 benefit year enrollee population. This commenter noted that any enrollee data used prior to the elimination of the shared responsibility payment would not reflect significant differences that could affect the risk profile and composition of the 2019 benefit year population.

Response: We are not finalizing any changes to the initial validation audit sample size at this time. HHS intends to revisit potential changes to initial validation audit sample sizes for future benefit years following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results. We note that 2017 risk adjustment data validation program year results are the most recent results that would be available in the 2019 benefit year, as a result of the operational timing of the risk adjustment data validation program. As such, we note that any approach to modify risk adjustment data validation sampling for an upcoming benefit year based on consideration of HCC failure rates, would rely on previous benefit year failure rates, as more recent data would not be available prior to when initial data validation samples are drawn.

Comment: A few commenters supported the proposal to vary the initial validation audit sample size based on HCC failure rates, sample precision, and issuer size as they believe larger sample sizes would help HHS meet desired precision targets and would lend additional credibility to risk adjustment data validation results. Another commenter encouraged HHS to increase the sample size as a means to potentially reduce data validation error rates. One commenter supported increasing sample size for the initial validation audit for those issuers that fall outside of the confidence interval. Several commenters supported the proposal to vary the initial validation audit sample size based only on issuer size, stating that sample sizes should be statistically significant and not capped at 200 or 400 for large issuers, and that larger sample sizes would increase the accuracy of the risk adjustment data validation results. Commenters also stated that if issuer size is used as a basis to determine the initial validation audit sample size, HHS should use the issuer's enrollment for the year that is being validated.

However, many other commenters did not support the proposal to vary sample size based on HCC failure rates, sample precision, and issuer size. One commenter stated HHS should only do so once there is sufficient credible experience with the HHS risk adjustment data validation program, citing concerns with making such changes based on 2017 benefit year data validation results, the first non-pilot risk adjustment data validation year under the HHS program. Another commenter did not support this proposal as they stated it effectively disincentives issuers from focusing on reducing their HCC failure rate because any issuer that is an outlier below the confidence interval threshold would be penalized by an increased sample size. The same commenter also noted the potential for annual variation in sample size would make it difficult for issuers to plan for staffing and resource needs.

Other commenters did not support varying the sample size based only on issuer size, expressing concerns over undue administrative burden related to obtaining medical records and substantiating diagnoses, the financial burden of increased administrative costs, and the resulting disruption to plans and the provider community without improving the quality of the data validation results. Yet another commenter stated that until electronic health record interoperability and widespread data sharing is implemented, increasing the sample size would create undue administrative burden.

Response: We share commenters' goals of increasing initial validation audit sample precision and ensuring the statistical validity of the sample, and while we believe that increased sample sizes could help achieve these goals, we are also sensitive to commenters' concerns about the burden of an increase to the sample size and the use of results from the first non-pilot year of risk adjustment data validation to establish larger sample sizes. However, while we recognize these concerns, we do not agree with comments that suggested that increased sample sizes will act as a disincentive for issuers to improve their failure rates. We believe that increasing sample size would

generally increase the sample precision, and could help issuers obtain more favorable risk adjustment data validation results by capturing enrollees with HCCs that may have been missed in smaller samples. We believe that this potential benefit would generally outweigh the additional costs of larger initial validation audit samples. As noted in this rule, we are not finalizing any increase to the initial validation audit sample size at this time, but intend to revisit these proposals and will consider the comments received on these proposals when we revisit potential changes to sample sizes for future benefit years.

Comment: One commenter supported the proposal to use 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year, while another commenter opposed the use of prior-year error rates in determining sample sizes. One commenter stated they believe the current risk adjustment data validation error estimation approach had several flaws that would not be adequately addressed by increasing the risk adjustment data validation sample size for certain issuers. The commenter stated that these flaws included basing adjustments to risk scores solely on risk adjustment data validation outlier status, the use of national benchmarks with large confidence intervals, and adjustment of coefficients by the difference between an outlier issuer's HCC group failure rate and the weighted mean HCC failure rate. The commenter stated that rather than increasing the sample size for certain issuers and building on a flawed process, HHS should reevaluate the risk adjustment data validation methodology in its entirety.

Another commenter opposed allowing issuers to request a larger sample size, stating that allowing such requests could provide opportunities for issuers to intentionally affect the data validation results of other issuers and disproportionately affect HCC failure rates and confidence intervals.

Several commenters suggested alternative approaches to vary the initial validation audit sample size. One commenter suggested adopting sample sizes based on statistical significance with a 90 percent confidence interval and suppression of positive outlier resampling for issuers that have demonstrated a low HCC error rate over multiple years. Another commenter stated HHS should replace the current random sample of 200 enrollees with a data-driven targeted process that identifies situations that warrant investigation. Another commenter recommended HHS evaluate ways to ensure providers' timely submission of the needed information and documentation to validate the diagnoses captured on the medical record(s). Another commenter did not agree that HHS should continue to use the Medicare Advantage risk score error rate data to determine precision, and recommended that HHS use the available commercial risk adjustment data starting with the 2020 benefit year of risk adjustment data validation. Another commenter stated that if larger sample sizes were adopted, issuers with plans in multiple states should be given the option to use the existing sample sizes for the initial validation audit.

Response: We remain interested in exploring ways to increase sample precision and the statistical validity of the initial validation audit sample and appreciate the different approaches offered. We are sensitive to commenters' concerns about the proposals outlined in the proposed rule and believe that further analysis is needed before making changes to sample sizes. Therefore, at this time, we are not finalizing any increase to the initial validation audit sample size and are maintaining the current sample size of 200 enrollees. We will revisit these proposals, along with the comments submitted, and may consider alternatives following consultation with stakeholders and further analysis of available data. We respond to comments on the risk adjustment data validation error estimation methodology in the preamble below.

b. Initial Validation Audit Sample Size—10th Stratum and Neyman Allocation (§ 153.630(b))

In the initial years of risk adjustment data validation, we constrained the ''10th stratum'' of the initial validation audit sample—that is, enrollees without HCCs selected for the initial validation audit sample—to be one-third of the sampled initial validation audit enrollees. Under this current approach, the remaining 9 age-risk strata were selected using a Neyman allocation [72] which optimizes the number of enrollees per stratum for the remaining two-thirds of sampled enrollees. Because we expected enrollees without HCCs to make up the majority of issuers' enrollees, in the absence of data from the individual and small group markets, we constrained stratum 10 to ensure that healthy enrollees were sampled in the initial years of risk adjustment data validation to establish adequate sampling assumptions.

In the proposed rule, we proposed to extend the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. Since a Neyman allocation approach is expected to provide a more optimal sample size allocation, we explained that we believe using the Neyman allocation for all strata would optimize issuers' initial validation samples and yield better precision than the one-third/two-thirds approach currently used in the enrollee initial validation audit sample. Further, an approach that permits for a larger portion of the sample to be allocated to the HCC strata as compared to the two-thirds allocation used in the current approach would result in a more robust HCC sample in support of the measurement of HCC failure rates under the HCC failure rate methodology finalized in the 2019 Payment Notice.[73] Finally, it would increase the probability of achieving our original target of 10 percent precision based on our historical observations of greater error rate variances among the HCC strata. We are finalizing the extension of the Neyman allocation sampling methodology to the 10th stratum, as proposed.

Comment: Some commenters supported extending the Neyman allocation sampling methodology to the 10th stratum, stating that doing so would effectively create an increase in the size of the sample actually available to validate the HCCs submitted to issuer EDGE servers. These commenters noted this approach would permit for a larger portion of the sample to be allocated to the HCC strata as compared to the two-thirds allocation used in the current approach, thereby resulting in a more robust HCC sample in support of the measurement of HCC failure rates under the HCC failure rate methodology finalized in the 2019 Payment Notice. However, other commenters did not support this proposal, as they were concerned that increasing the number of sampled members with HCCs would create undue administrative and financial burden on plans and the provider community without improving the quality of the data validation results or addressing their perceived flaws of the risk adjustment data validation sampling.

[72] Neyman allocation is a method to allocate samples to strata based on the strata's variances and similar sampling costs in the strata. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See *http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml.*

[73] 83 FR 16930 at 16961 (April 17, 2018).

Response: We are finalizing the extension of the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. As noted by some commenters, this is expected to provide a more optimal sample size allocation than the current one-third/two-thirds approach. We believe this will also allow us to achieve greater precision in the HCC error rate methodology by expanding the portion of the sample that may be allocated to the HCC strata (that is, strata 1 through 9) because of the potential for a more robust HCC sample than the current approach provides. We are finalizing the extension of the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. As noted by some commenters, this is expected to provide a more optimal sample size allocation than the current one-third/two-thirds approach. We believe this will also allow us to achieve greater precision in the HCC error rate methodology by expanding the portion of the sample that may be allocated to the HCC strata (that is, strata 1 through 10) because of the potential for a more robust HCC sample than the current approach provides. We further believe that the benefits of more accurate initial validation samples generally outweigh the additional burden of increased sample sizes by capturing enrollees with HCCs that may have been missed in smaller samples. However, as discussed above, we will monitor the impact of this change and continue to consider modifications to the initial validation audit sampling approach for future benefit years in consultation with stakeholders.

c. Second Validation Audit Findings and Error Rate Discrepancy Reporting (§ 153.630(d)(2))

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the second validation audit or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. We proposed to amend paragraph (d)(2) to shorten the window to confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2018 benefit year risk adjustment data validation. In light of comments received, we will not shorten the timeframe under § 153.630(d)(2) to 15 calendar days at this time, and will maintain the existing 30-calendar day window for issuers to confirm the findings of the second validation audit (if applicable) or the calculation or the risk score error rate.

We also clarified in the proposed rule that there are two discrepancy reporting windows under § 153.630(d)(2). First, at the conclusion of the second validation audit, we will distribute to issuers their second validation audit findings in the event there is insufficient agreement between the initial and second validation audit results during the pairwise means analysis, and the second validation audit findings will be used for the risk score error rate calculation. The window for issuers who receive second validation audit findings to confirm the findings or file a discrepancy, in a manner set forth by HHS, would begin when the second validation audit findings reports are issued. Second, at the conclusion of the risk score error rate calculation process, we will distribute the risk score error rate calculation results to all issuers for the given benefit year. Once the risk score error rate calculation results are distributed, the window to confirm the results or file a discrepancy, in the manner set forth by HHS, would begin.

We reiterated, consistent with the approach finalized in the 2018 Payment Notice, that issuers are not permitted to appeal the resolution of any discrepancy disputing the initial validation audit sample, or to file a discrepancy or appeal the results of the initial validation audit.[74] As detailed in the 2015 Payment Notice [75] and discussed later in this final rule, if sufficient pairwise means agreement is achieved, the initial validation audit findings will be used for purposes of the risk score error rate calculation, and therefore, those issuers will only be permitted to file a discrepancy or appeal the risk score error rate calculation.

Finally, we proposed to amend § 153.630(d)(2) to replace the phrase ''audit and error rate'' for which an issuer must confirm or file a discrepancy that appears at the end of the provision with ''the findings of the second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.'' We are finalizing the amendments to § 153.630(d)(2) as proposed, except for the proposed shortening of the applicable timeframe from 15 to 30 calendar days.

The following is a summary of the public comments we received on our proposals regarding the second validation audit findings and risk score error rate discrepancy reporting windows under § 153.630(d)(2).

Comment: Commenters overwhelmingly opposed shortening the discrepancy windows for risk adjustment data validation, with a few suggesting that HHS revisit the idea after a non-pilot year of risk adjustment data validation has occurred. Several commenters suggested we examine other areas of the risk adjustment data validation timeline to possibly make shorter.

Response: In light of comments received, we are not finalizing the proposal to shorten the discrepancy reporting window under § 153.630(d)(2) from 30 to 15 calendar days. Although 15 calendar days is consistent with the initial validation audit sample and EDGE discrepancy submission windows,[76] we agree that such a change should not be made until after completion of the first non-pilot year of risk adjustment data validation and we have more experience with the process. Additionally, we will continue to examine opportunities to refine the risk adjustment data validation timeline for future benefit years.

d. Default Data Validation Charge

Under § 153.630(b)(10), if an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or submit initial validation audit results, we impose a ''default data validation charge,'' which the regulation currently refers to in paragraph (b)(10) as a ''default risk adjustment charge.'' As explained in the 2015 Payment Notice, the default data validation charge is calculated in the same manner as the default risk adjustment charge under § 153.740(b).[77] With the 2017 benefit year being the first non-pilot year of risk adjustment data validation, and the first year for which HHS may impose the default data validation charge for noncompliance with applicable data validation requirements, we proposed several amendments to further distinguish the default data validation charge assessed under § 153.630(b)(10) from the default risk adjustment charge assessed under § 153.740(b). First, we proposed to amend § 153.630(b)(10) to replace the phrase ''HHS will impose a default risk adjustment charge'' with ''HHS will impose a default data validation charge.'' This change is intended to more clearly distinguish

[74] 81 FR 94106.

[75] See 78 FR at 72334 through 72337 and 79 FR at 13761 through 13768.

[76] See §§ 153.630(d)(1) and 153.710(d).

[77] 79 FR at 13769.

between the two separate risk adjustment-related default charges. Second, we proposed to modify how the default data validation charge under § 153.630(b)(10) would be calculated. While we would generally continue to calculate the default data validation charge in the same manner as the risk adjustment default charge under § 153.740(b), we proposed to calculate the default data validation charge based on the enrollment for the benefit year being audited in risk adjustment data validation, rather than the benefit year during which transfers would be adjusted as a result of risk adjustment data validation. By way of example, if an issuer is subject to the default data validation charge for the 2021 benefit year risk adjustment data validation and it offers risk adjustment covered plans in the same state market risk pool in the 2022 benefit year, its default data validation charge would be calculated based on 2021 benefit year enrollment data (rather than 2022 benefit year enrollment data). Under this example, the default data validation charge this issuer would receive for failing to comply with the 2021 benefit year risk adjustment data validation requirements would equal a per member per month (PMPM) amount for the 2021 benefit year multiplied by the plan's enrollment for the 2021 benefit year as follows:

$T_n = C_n * E_n$

Where:

T_n = total default data validation charge for a plan *n;*

C_n = the PMPM amount for plan *n;*[78] and

E_n = the total enrollment (total billable member months) for plan *n*.[79]

Third, we proposed to amend the allocation approach for distribution of default data validation charges among issuers. We proposed to allocate a default data validation charge to the risk adjustment data validation issuers that were part of the same benefit year risk pool(s) as the noncompliant issuer. However, we would not allocate default data validation charges to any other noncompliant issuers in the same benefit year risk pool(s). This approach is consistent with the methodology for allocating the default risk adjustment charges under § 153.740(b), and includes all issuers in the same benefit year risk pool(s) that could be subject to a risk score adjustment as the result of other issuers' risk adjustment data validation results. Issuers in the same benefit year risk pool(s) that are exempt from the risk adjustment data validation requirements would also be included in the allocation of any default data validation charges. Therefore, we proposed to allocate any default data validation charges collected from noncompliant issuers among the compliant and exempt issuers in the same benefit year risk pool(s) in proportion to their respective market shares and risk adjustment transfer amounts for the benefit year being audited for risk adjustment data validation.

As an illustrative example, assume there are 4 issuers (A, B, C, and D) in the individual non-catastrophic risk pool in state X for the 2017 benefit year, and an additional issuer, E, in the 2018 benefit year individual non-catastrophic risk pool in state X. Assume:

- Issuer A does not comply with risk adjustment data validation requirements for the 2017 benefit year and is assessed a default data validation charge.
- Issuer B was exempt from risk adjustment data validation for the 2017 benefit year because it was a small issuer (that is, it had 500 or fewer billable member months statewide in state X).
- Issuers C and D complied with applicable 2017 benefit year risk adjustment data validation requirements.
- Issuer E was not in the individual non-catastrophic risk pool in state X for 2017.

Issuer A's default data validation charge would be allocated to issuers B, C, and D in proportion to their 2017 benefit year transfer amounts and market shares. While Issuer B was not subject to risk adjustment data validation for the 2017 benefit year, it was still part of the same state market risk pool and would be subject to possible risk score adjustments due to the risk adjustment data validation results of Issuers C and D. Since Issuers C and D also participated in the individual non-catastrophic risk pool in state X for 2017 and complied with applicable data validation requirements, they would also receive part of Issuer A's default data validation charge. However, Issuer E was not part of the individual non-catastrophic risk pool in state X until the 2018 benefit year, and therefore, would not receive any part of Issuer A's 2017 benefit year default data validation charge.

In the proposed rule, we noted that we intend to publish the default data validation charge information in the benefit year's report(s) released under § 153.310(e) in which transfers are adjusted based on risk adjustment data validation results. We also explained that, following release of the report under § 153.310(e), these amounts would then be included as part of the monthly payment and collection processes described in § 156.1215 alongside the collection of risk adjustment charges and payments calculated under the HHS risk adjustment methodology for the applicable benefit year.

Fourth, we clarified that a default data validation charge under § 153.630(b)(10) is separate from risk adjustment transfers for a given benefit year, unlike a default risk adjustment charge under § 153.740(b), which replaces the issuer's transfer amount for that benefit year. For example, if an issuer fails to submit initial validation audit results for the 2017 benefit year, it would receive a default data validation charge based on 2017 benefit year data calculated in accordance with the formula outlined in this final rule. This default data validation charge for the 2017 benefit year would be in addition to, and separate from, the issuer's 2018 benefit year risk adjustment payment or charge amount as calculated under the HHS-operated risk adjustment methodology. This means that an issuer may owe both a risk adjustment charge and a default data validation charge (for example, an issuer could owe a risk adjustment charge for the 2018 benefit year and a default data validation charge for the 2017 benefit year risk adjustment data validation). Similarly, an issuer may owe a default risk adjustment charge for a given benefit year, alongside a default data validation charge for the benefit year being audited (for example, an issuer could owe a default risk adjustment charge for the 2018 benefit year, as well as a default data validation charge for the 2017 benefit year).

We offered these proposals and clarifications about how HHS will assess and allocate the default data validation charge at this time to allow issuers to better understand the

[78] Except as otherwise provided in this final rule, the default data validation charge is calculated in the same manner as the risk adjustment default charge under § 153.740(b). See 79 FR at 13769. As established in the 2015 Payment Notice, a PMPM default charge is equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. See 79 FR at 13790. While this percentile was subsequently adjusted to the 90th percentile in the 2017 Payment Notice, the PMPM amount is otherwise calculated in the same manner. See 81 FR at 12237. The 2020 Payment Notice proposed rule did not propose, and this final rule does not make, any changes to this aspect of the calculation of the default data validation charge.

In the 2015 Payment Notice at 79 FR 13790, we provided that E_n could be calculated using an enrollment count provided by the issuer, enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or other reliable data sources. The proposed rule did not propose, and this final rule does not make, any changes to the sources that could be used.

[79] Ibid.

implications of noncompliance with initial validation audit requirements as risk adjustment data validation operations transition away from the pilot years of the program.

We are finalizing the amendments to § 153.630(b)(10), as well as the proposed changes to the calculation and allocation of the default data validation charge, as proposed. As outlined further below, we are modifying the timing for publication, collection and distribution of the default data validation charges.

Comment: Commenters were in favor of basing the default data validation charge on the enrollment of the year being audited rather than the year being adjusted. One commenter requested that we clarify the allocation methodology for issuers that have exited the market.

Response: We are finalizing the proposals related to the default data validation charge, but are modifying the timing for publication, collection, and distribution of the default data validation charges. Rather than releasing this information as part of the annual summary risk adjustment transfer report released by June 30, information on default data validation charges and allocations will be published as part of the separate announcement of risk adjustment data validation results and related adjustments to risk adjustment transfers for the applicable benefit year so that issuers will not have to consult multiple reports for information on payments and charges related to risk adjustment data validation. Default data validation charge amounts will be included as part of the monthly payment and collection processes described in § 156.1215 alongside the collection and distribution of the risk adjustment data validation-related adjustments to risk adjustment transfers. Please refer to the preamble section below on negative error rate outlier markets for further details on the updated timeline for publication of risk adjustment data validation results, as well as collection and disbursement of risk adjustment data validation related adjustments to risk adjustment transfers.

We clarify that if an issuer is in a state market risk pool with a noncompliant issuer in a given benefit year, and then exits the state market risk pool in the subsequent benefit year, it will still be eligible to receive its portion of the allocation from the noncompliant issuer's default data validation charge. This approach is consistent with the general policy established in the 2019 Payment Notice [80] to adjust exiting issuers' risk adjustment transfers based on risk adjustment data validation results, and it allows those who are compliant with applicable risk adjustment data validation related adjustments to gain the benefit of an allocation amount.

e. Second Validation Audit Pairwise Means Test

In the 2014 Payment Notice, we provided that a second validation audit will be conducted by an entity retained by HHS to verify the accuracy of the findings of the initial validation audit.[81] Consistent with § 153.630(c), HHS must select a subsample of the risk adjustment data validated by the initial validation audit for the second validation audit. In the 2015 Payment Notice, we indicated that to select the subsample, the second validation auditor will use a sampling methodology that allows for pairwise means testing to establish a statistical difference between the initial and second validation audit results.[82] This pairwise means test uses a 95 percent confidence interval (and a standard deviation of 1.96). To do pairwise means testing under the current approach, the second validation auditor tests a subsample of enrollees from an issuer's initial validation audit sample of 200 enrollees. If the pairwise means test results for a subsample indicate that the difference in enrollee results between the initial and second validation audits is not statistically significant, the initial validation audit results are used for calculation of HCC failure rates and risk score error rates. If the pairwise means test results for the subsample yield a statistically significant difference, the second validation auditor performs another validation audit on a larger subsample of enrollees from the initial validation audit. The results from the second validation audit of the larger subsample are again compared to the results of the initial validation audit using the pairwise means test with a subsample size of up to 100 enrollees. If there is no statistically significant difference between the initial and second validation audits of the larger subsample, HHS will apply the initial validation audit error results to calculate the HCC failure rates and risk score error rates. However, if a statistically significant difference is found based on the second validation audit of the larger subsample up to 100 enrollees, HHS will apply the second validation audit results to the larger subsample to calculate the HCC failure rates and risk score error rates.

Based on the results of the second validation audit for the 2016 risk adjustment data validation pilot year, we proposed to modify the statistical subsampling methodology to further expand the comparison of results between the initial and second validation audits. Specifically, when the larger subsample (of up to 100 enrollees) results indicate a statistically significant difference, we believe that further sampling by the second validation auditor is necessary and appropriate to determine whether the second validation audit results from the full sample should be used in place of the initial validation audit results. Therefore, we proposed that, if a statistically significant difference is found based on the second validation audit of the larger subsample (of up to 100 enrollees), HHS would expand its sample to the full initial validation audit sample to consider whether the second validation audit results of the full sample or the subsample (of up to 100 enrollees) results should be used in place of initial validation audit results. Allowing the further testing of the sample provides assurance and confidence in the second validation audit results and the associated error estimation rate that will ultimately be used to adjust risk scores and transfers.

To determine whether to expand the second validation audit to the full initial validation audit sample, we proposed to use a precision analysis. We proposed to use precision metrics, including the standard error and confidence intervals, to determine if the second validation audit review of the larger subsample (of up to 100 enrollees) is of high or low precision. If the results of the second validation audit precision analysis determined that the precision level is high, we proposed that HHS would use the second validation audit results for the larger subsample (of up to 100 enrollees) in place of the initial validation audit results for the error estimation and calculation of adjustments for plan average risk score, as applicable. However, if the second validation audit precision analysis for a larger subsample (of up to 100 enrollees) determined that the precision level was low, the second validation audit would expand and use the full initial validation audit sample of 200 enrollees for error estimation and calculation of adjustments for plan average risk score.

We are finalizing this approach as proposed.

Comment: One commenter stated that it believed the proposal would not substantially improve the process.

[80] 83 FR 16965.

[81] 78 FR 15437.

[82] 79 FR 13761.

Another commenter did not explicitly oppose the proposal, but suggested better pairwise accuracy could be achieved through increased education and outreach.

Response: HHS has an interest in providing issuers every opportunity to use the results submitted by the initial validation audit entity and attested to by the issuer before taking the step of replacing those results with second validation audit findings. Expanding the subsample further and then testing precision when the larger subsample (of up to 100 enrollees) results indicate a statistically significant difference allows additional opportunity to find the initial validation audit findings are valid. We disagree with the commenter that these proposals would not substantially improve the process. On the contrary, we believe that allowing further testing of the sample provides assurance and confidence in the audit results and the associated error estimation rate that will ultimately be used to adjust risk scores and transfers. Therefore, we are finalizing this approach as proposed. We remain committed to providing training and support as needed to improve the initial validation audit process and subsequent pairwise results.

f. Error Estimation for Prescription Drugs

In the proposed rule, we proposed several options for incorporating RXCs in the risk adjustment data validation processes beginning with the 2018 benefit year risk adjustment data validation. Because the incorporation of payment RXCs into the risk adjustment models for adults began with the 2018 benefit year, we discussed whether modification was appropriate to the error estimation methodology to take into account the RXC failure rates as part of the HHS risk adjustment data validation process and we proposed various ways to incorporate RXCs into risk adjustment data validation processes, including adding RXCs to the error estimation methodology by treating RXCs similar to HCCs.

The first proposal that we outlined would incorporate RXCs into the HCC failure rate methodology by adding each RXC as a separate factor, similar to an ''HCC'', for classification into the low, medium, and high HCC groups determined by the national failure rates for each RXC. To apply this change to the error estimation methodology finalized in the 2019 Payment Notice, we proposed the definition of superscript *h* would expand to a list of codes including both the 128 HCCs and 12 RXCs whereby HHS would first calculate the failure rate for each HCC and RXC in issuers' samples as:

$$FR^{h_r} = 1 - \frac{Freq_IVA^{h_r}}{Freq_EDGE^{h_r}}$$

Where:

h_r is the set of codes including 128 HHS HCCs and 12 RXCs.

$Freq_EDGE^{h\text{-}r}$ is the frequency of HCC code h or RXC code r occurring on EDGE, which is the number of sampled enrollees recording HCC code h or RXC code r on EDGE.

$Freq_IVA^{h\text{-}r}$ is the frequency of HCC code h or RXC code r occurring in initial validation audit results, which is the number of sampled enrollees with HCC code h or RXC code r in initial validation audit results.

$FR^{h\text{-}r}$ is the failure rate of HCC code h or RXC code r.

HHS would then create three ''HCC/RXC'' groups based on the HCC failure rates and RXC failure rates derived in the above calculation. These ''HCC/RXC'' failure rate groups would rank all HCC failure rates and RXC failure rates to assign each unique HCC and RXC in the initial validation audit samples to a high, medium, or low failure rate group. To assign each HCC and RXC to a ''HCC/RXC'' failure rate group, we proposed to use the current HCC failure rate ranking methodology that ranks each HCC/RXC failure rate divided into three groupings based on weighted total observations or frequencies of that HCC/RXC across all issuers' initial validation sample, or assigning HCCs and RXCs failure rates by taking into consideration the ranking of related HCCs and RXCs in the grouping. Under this approach, we would maintain a single classification for HCC and RXC high, medium, or low groups, instead of creating two separate classifications of RXCs and single component HCCs.

Alternatively, we proposed incorporating RXCs as a separate ''HCC'' grouping in the error estimation methodology. Under this approach, we would keep the 128 HCCs in the three groups, but combine all RXCs into an additional, fourth separate group. Therefore, separate RXC and HCCs groups would be created, and their failure rates would be computed within those four groupings. This approach to group RXCs would be the same as for HCC groupings, which is based on the failure rates FR^r of the 12 RXCs:

$$FR^r = 1 - \frac{Freq_IVA^r}{Freq_EDGE^r}$$

Where:

r is the set of 12 RXCs.

$Freq_EDGE^r$ is the frequency of RXC code r occurring on EDGE, which is the number of sampled enrollees recording RXC code r on EDGE.

$Freq_IVA^r$ is the frequency of RXC code r occurring in initial validation audit results, which is the number of sampled enrollees with RXC code r in initial validation audit results.

FR^r is the failure rate of RXC code r.

While we assumed that RXCs may be easier to validate, this proposed approach could take into consideration the potential differing failure rates within the RXC groupings as opposed to the single component HCC groupings, or isolate the RXC failure rates to a separate grouping from HCCs before applying those failure rates to the error rate calculation. This alternative approach would have also resulted in an additional grouping in the error estimation methodology, and having more groupings means that the number of groupings where it is possible for an issuer to be an outlier would increase. Further, in the event that all RXCs do not have similar, low failure rates, the confidence interval for an RXC-only group could be quite large, resulting in a significant difference between the outliers' failure rates to the group's failure rate mean, and by extension, could result in a larger failure rate adjustment factor for the RXC-only group.

In addition to adopting one of the above approaches to group RXCs as part of the error estimation methodology, we would also need to incorporate RXCs into the error rate calculation under the error estimation methodology. To do so, we proposed three alternative approaches to incorporate and adjust for RXCs and RXC–HCC interaction factors in the error rate calculation.

One option that we proposed to incorporate the RXCs in the error rate calculation was to add RXCs to the current methodology of calculating error rates, without accounting for any HCC–RXC interaction factors. To incorporate RXCs in the current error rate calculation under this option, we proposed to modify the formula to calculate an enrollee's adjustment $Adjustment_{i,e}$ as follows:

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$$Adjustment_{i,e} = \frac{\sum_c \left(RS_{i,e}^{c,G} * Adjustment_i^G \right)}{\sum_c \left(RS_{i,e}^{c,G} \right)}$$

Where:

$RS_{i,e}^{c,G}$ is the risk score component of a single HCC or RXC code c (belonging to HCC/RXC group G) recorded on EDGE for Enrollee e of Issuer i.

This approach would be the simplest approach to adjusting RXCs in the error rate calculation, as $RS_{i,e}^{c,G}$ generally retains the same definition as in the 2019 Payment Notice[83] for $RS_{i,e}^{hcc,G}$ and the resulting calculation would be completed as follows:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hhc/rxc,G}$$

Where:

$RS_{i,e}^{c_hhc/rxc,G}$ is the risk score component of a code *c* as a single HCC or RXC, without considering the interaction coefficients between code *c* and other codes for Enrollee *e* of Issuer *i*. However, this approach would mean that the interaction of the risk score coefficients between the single component HCC and the RXC would not be considered in the error rate calculation, which may be an oversimplification of this calculation.

As a second alternative, we solicited comments on the adjustment of the RXCs in the error rate calculation as part of the risk score coefficient for a single component HCC by adjusting the risk score coefficient of the RXC-HCC interaction factor, if the coefficient exists. This step would start with the coefficient for a single component HCC and RXC and then adjust both single component coefficients with the full interaction term for both the HCC and RXC to calculate the error rate. Under this approach, if there is no coefficient, the single component HCC and RXC would not be adjusted by an interaction term. Under this approach, $RS_{i,e}^{c,G}$ would be defined as:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hcc/rxc,G} + RS_{i,e}^{c_x_hXr,G}$$

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[83] 83 FR 16930 at 16963.

Where:

$RS_{i,e}^{c_hcc/rxc,G}$ is the risk score component of a code *c* as a single HCC or RXC, without considering the interaction coefficients between code *c* and other codes for Enrollee *e* of Issuer *i*.

$RS_{i,e}^{c_x_hXr,G}$ is the risk coefficient for the interaction between an HCC and an RXC, with the interaction term existing between code *c* and another code *x* for Enrollee *e* of Issuer *i.*

G is the HCC/RXC group for code *c.*

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The purpose of this second alternative for incorporating RXCs in the error rate calculation was to capture the sampled enrollee's characteristics and interaction between the single component HCC and RXC that may provide a more accurate calculation than not accounting for any interaction between the single component HCC and RXC. However, this approach would have added an additional step to the error rate calculation, whereby the risk score coefficient for a condition would be adjusted by the interaction coefficients between the single component HCC and the RXC and would have taken into account the full interaction coefficient separately for the HCC and RXC, which may result in an over-adjustment for the interaction terms.

A third alternative to incorporating RXCs as part of the error rate calculation would be to adjust the risk score coefficient for a single component HCC and RXC by a modified interaction coefficient between the single component HCC and RXC indicator, if the coefficient exists. If there is no coefficient, the single component HCC and the RXC would not be adjusted by an interaction coefficient. This alternative approach was intended to capture a sampled enrollee's specific characteristics and interaction between HCC and RXC and modify the interaction such that the total adjustments are equal to the total interaction term value.

We also generally solicited comment on how to weight risk score coefficients and account for the interaction terms between the single component HCC and the RXCs in calculating the error rate under these alternative proposed approaches. Additionally, in the error estimation methodology finalized in the 2019 Payment Notice, we did not include the severity illness indicator interactions for HCCs as they can be triggered by multiple combinations of HCCs, which would be overly complex to implement. As part of our current evaluation of the impact of adjusting for the RXC–HCC interactions in the error estimation methodology, we also sought comment on whether we should similarly not adjust for the RXC–HCC interactions.

We solicited comment on all of these proposed approaches for incorporating RXCs into the error estimation methodology and error rate calculation, including whether we should consider alternative options.

Finally, as an alternative to the aforementioned proposed policies, we stated that we were also considering methods for incorporating RXCs (or all drugs) into the risk adjustment data validation process other than as part of the error estimation methodology and error rate calculation. We proposed an option to treat RXC errors as a data submission issue. Specifically, under this approach, we would incorporate RXCs or all drugs into risk adjustment data validation as a method of discovering materially incorrect EDGE server data submissions in the same or similar manner to how we address demographic and enrollment errors discovered during risk adjustment data validation.[84] Under this approach, instead of incorporating RXCs into the error estimation methodology and error rate calculation, we would treat RXC or general drug errors discovered during risk adjustment data validation in a manner similar to an EDGE data discrepancy, which is addressed in the current benefit year under § 153.710(d). As such, these RXC or general drug errors would be the basis for an adjustment to the applicable benefit year risk score and original transfer amount, rather than the subsequent benefit year risk score. Any material errors identified through this process would result in a decrease to the issuer's original risk score, thereby resulting in a reduced risk adjustment payment or an increased risk adjustment charge for that issuer. If this alternative approach were adopted, the identification of RXC or general drug errors could also have the effect of reducing charges or increasing payments to other issuers in the state market risk pool, holding constant the other elements of the state payment transfer formula, due to the budget neutral framework for the HHS operated program. We solicited comment on this alternative approach, especially in comparison to the proposals for incorporating RXCs into the error estimation methodology or error rate calculation, and on whether other specific requirements would be needed to verify materiality of risk score impacts if we were to treat RXC or general drug errors discovered during risk adjustment data validation as a data submission issue through the EDGE data discrepancy process under § 153.710(d).

After consideration of the comments received, we are finalizing an approach under which we will incorporate RXCs into risk adjustment data validation as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during risk adjustment data validation, and will pilot the incorporation of these drugs into the risk adjustment data validation process for the 2018 benefit year. As a pilot year, the identification of RXC errors during the 2018 benefit year risk adjustment data validation process will not be used to adjust 2018 risk scores or transfers.

Comment: While some commenters generally supported adding RXCs to the error estimation methodology, many commenters discouraged HHS from doing so because they did not generally believe that adding this complexity to the error estimation methodology would deliver improved risk adjustment data validation results, and expressed

[84] See 83 FR 16930 at 16970 through 16971.

concern that it instead would increase administrative and financial burden for issuers and the provider community. Some commenters were concerned about making changes to the error estimation methodology when issuers have not yet seen the first non-pilot year of risk adjustment data validation results. Some commenters recommended retaining the current error estimation methodology that focuses on validating HCCs and not expanding the error rate methodology to include RXCs, while one commenter noted the proposed rule did not address changes that would be made to the member-level risk score adjustment calculation. Some commenters recommended that further consideration be given to the value of including RXC related errors before incorporating RXCs (or all drugs) as part of the data validation process. However, several other commenters supported treating RXCs in a manner similar to how we address demographic and enrollment errors discovered during the data validation process (or an EDGE server data discrepancy) as a more efficient and less complicated process than the other options.

Response: As discussed in the proposed rule, we recognize there may be differences between HCCs and RXCs that need to be considered when incorporating RXCs into risk adjustment data validation. For example, it may be more straightforward for initial validation auditors to validate an RXC rather than an HCC because HCC validation requires recoding a medical record, with a potential for greater variation. However, given the incorporation of RXCs into the HHS risk adjustment adult models beginning with the 2018 benefit year and their ability to affect an issuer's risk score and calculated transfers in the state market risk pool, we believe it is important that RXCs are validated in some manner as part of risk adjustment data validation. Therefore, based on comments received, we are finalizing an approach, starting with 2018 benefit year risk adjustment data validation, under which we will incorporate RXCs into risk adjustment data validation in a manner similar to how we address demographic and enrollment errors discovered during the data validation process. This approach will not affect or require changes to the error estimation methodology, including calculation of the individual member error rate, which was finalized in the 2019 Payment Notice.[85] That is, RXC failures will not be measured as part of the HCC failure rates used to adjust enrollees' risk scores, but will be treated as an EDGE discrepancy. This approach will ensure that RXCs are being validated while limiting burden to issuers and providers to validate these RXCs. Furthermore, for consistency with the EDGE server data discrepancy process and the policy regarding adjustments to transfers due to submission of incorrect data[86], we are finalizing that RXC errors will only result in a reduced risk adjustment payment or an increased risk adjustment charge for that discrepant issuer with the errors and will not result in increased payment or decreased charges for that issuer.

Additionally, in response to comments, we are finalizing a policy to treat the incorporation of RXCs into 2018 benefit year risk adjustment data validation as a pilot year to allow HHS and issuers to gain experience in validating RXCs before RXCs are used to adjust issuers' risk scores. This approach will also allow for HHS and issuers to primarily focus efforts and resources on validating HCCs in the 2018 benefit year risk adjustment data validation and understanding the first year of risk adjustment data validation results, which issuers will receive later this year (reflecting 2017 benefit year data validation results).

Comment: Several commenters suggested piloting the incorporation of RXCs into the risk adjustment data validation process to gain experience in how best to evaluate RXC errors and understand potential implications in the risk adjustment data validation process. Some of these commenters recommended a pilot for 2 years to allow HHS, issuers and other stakeholders to gain experience with the incorporation of RXCs into the risk adjustment data validation process. Other commenters requested that HHS postpone the implementation of RXCs in risk adjustment data validation or focus current data validation efforts on HCCs. One of these commenters noted that HHS would have the means to address any obvious fraudulent activity regarding RXCs discovered as part of a pilot process.

Response: We are finalizing the incorporation of RXCs in risk adjustment data validation beginning with the 2018 benefit year. However, in response to comments, we will treat the 2018 benefit year as a pilot year for purposes of incorporating RXCs, similar to the pilot years that we allowed for other aspects of risk adjustment data validation for the 2015 and 2016 benefit years. Under this approach, the risk adjustment data validation processes will proceed for the 2018 benefit year in a similar manner as the 2017 benefit year, with the addition of RXCs being included and treated in a manner similar to how we treat demographic and enrollment errors during data validation. However, the identification of RXC errors as part of 2018 risk adjustment data validation will not be used to adjust risk scores. While we do not agree with commenters that piloting RXCs in risk adjustment data validation for 2 years is necessary at this time, we agree with commenters who suggested that piloting the incorporation of RXCs in risk adjustment data validation for the 2018 benefit year will provide HHS, issuers, and stakeholders with experience in validating RXCs and understanding potential implications before using identified RXC errors to adjust risk scores. Our intention at this time is to fully implement the incorporation of RXCs into risk adjustment data validation, as outlined in this final rule, beginning with the 2019 benefit year of risk adjustment data validation.

Comment: Commenters wanted additional information on how HHS plans to validate RXCs, with one commenter recommending a verification approach where the audit would confirm that the prescription is a valid paid claim by reviewing this information on issuers' source systems (similar to how demographic and enrollment data is validated in risk adjustment data validation), and not obtain the actual prescription, which a commenter thought would be burdensome and would lead to false results. Some commenters sought clarification as to what constitutes a valid prescription that would need to be obtained to validate the RXC and what would be considered acceptable documentation within the medical record system for the purposes of validating the RXC. One commenter, who wanted clarification on how HHS determines the materiality of errors and the size of the adjustment for data discrepancies, noted that issuers may not have the ability to provide other types of documentation to validate that a prescription was written by a provider, and another commenter stated that as long as the issuer paid for the drug, it would be difficult to see how the issuer acted in bad faith and that applying a data validation process that makes sure the issuer's claims and payments match what is reported to

[85] 83 FR 16930 at 16961–16966.

[86] See the November 15, 2018, *Evaluation of EDGE Data Submissions for the 2018 Benefit Year Guidance,* available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf.* Also see 83 FR at 16970–16971.

EDGE is the only validation that might identify potential inappropriate or fraudulent actions. Other commenters suggested varying types of collaboration with stakeholders on methodology and documentation standards related to incorporation of RXCs into risk adjustment data validation.

Response: As discussed in the 2018 Payment Notice,[87] HHS does not perform risk adjustment data validation audits with the intent of determining whether a clinician correctly diagnosed a patient. Rather, HHS focuses on ensuring that enrollees' diagnoses on paid claims reflect the appropriately assigned HCCs and were diagnosed by a licensed clinician. Likewise, in validating pharmacy claims, we intend to validate factors such as whether the prescription was paid by the issuer, and whether the RXC eligible service code on a medical claim was paid by the issuer.

We believe that this type of approach to RXCs will be an effective approach for validating that issuers are providing accurate RXC claims information while limiting the burden on issuers and other stakeholders involved in the risk adjustment data validation process. Specifically, to validate RXCs in risk adjustment data validation, we will conduct a claims-based validation to evaluate the accuracy of RXC data submissions. Under this approach, similar to how we confirm demographic and enrollment data during the risk adjustment data validation process, we will not require the issuer to obtain a valid prescription for the RXC and will only subject issuers' source system documentation of pharmacy claims or medical claims to the initial validation auditor and second validation auditor review, thereby limiting the burden on issuers to validate the RXCs.[88] Consistent with the treatment of demographic and enrollment errors discovered during data validation,[89] we intend to communicate with issuers where significant RXC errors are found.

Furthermore, in a non-pilot year, we would only adjust issuer risk scores for RXC errors in cases where an issuer has materially incorrect EDGE server RXC data submissions, and these discovered RXC errors would be the basis for an adjustment to the applicable benefit year transfer amount for the state market risk pools in question. We will work with these issuers to resolve potential discrepancies in a manner similar to the EDGE data submission discrepancy process.[90] We also intend to be in communication with all issuers in affected state market risk pools throughout the second validation audit process when RXC errors or other identified data validation errors could result in adjustments to risk adjustment transfers.

This approach will target materially incorrect RXC data and will not target an isolated RXC data error, which is similar to the goal of the error estimation methodology for HCCs finalized in the 2019 Payment Notice—to avoid adjusting all issuers' risk adjustment transfers for expected variation. The approach is also similar to how demographic and enrollment validation is occurring where the review involves the identification of errors that could result in the initiation of a discrepancy process for adjustments.[91] Additionally, we intend to learn from the experience of validating RXCs during the pilot year to inform and potentially refine the approach for incorporating review of RXCs in data validation in future benefit years. However, as noted above, our intention at this time is to fully implement the incorporation of RXCs into risk adjustment data validation, as outlined in this final rule, beginning with the 2019 benefit year of risk adjustment data validation.

g. Risk Adjustment Data Validation Adjustments in Exiting and Single Issuer Markets and Negative Error Rate Outlier Markets

i. Risk Adjustment Data Validation Adjustments in Exiting Issuer Markets

Under the risk adjustment data validation program, adjustments to transfers are generally made in the benefit year following the benefit year that was audited. For issuers that exit the market following the benefit year being audited, and therefore do not have transfers to adjust during the following benefit year, we previously finalized an exception to this general rule such that we will adjust the exiting issuer's prior year risk scores and associated transfers where it has been identified as an outlier through the HCC failure rate methodology during risk adjustment data validation.[92] In the proposed rule, we proposed to amend our policy to provide that, if an exiting issuer is found to be a negative error rate outlier, HHS would not make adjustments to that issuer's risk score and its associated risk adjustment transfers as a result of this negative error rate outlier finding. A negative error rate will have the effect of increasing an issuer's risk score and thereby increasing its calculated risk adjustment payment or reducing its calculated risk adjustment charge. To avoid retroactively re-opening a risk pool to make adjustments to other issuers' transfers based on an exiting issuer's negative error rate, we proposed to re-open the issuer's risk score and its associated risk adjustment transfers in a prior benefit year only if the exiting issuer was found to have had a positive error rate, and was therefore overpaid or undercharged based on its risk adjustment data validation results. When the exiting issuer is a positive error rate outlier, HHS would collect funds (either increasing the charge amount or reducing the payment amount) from the exiting issuer and redistribute the amounts to other issuers who participated in the same state market risk pool in the prior benefit year. This approach was intended to help ensure that issuers are made whole even if an issuer with a positive error rate exits the state, without the additional burdens associated with having transfers adjusted (including the potential for additional charges being assessed) for a prior benefit year for a negative error rate outlier when an issuer decides to exit a state.

Further, we proposed that to be considered an exiting issuer under this policy, the issuer would have to exit all of the markets and risk pools in the state (that is, not selling or offering any new plans in the state). If an issuer only exits some markets or risk pools in the state, but continues to sell or offer new plans in others, it would not be considered an exiting issuer under this policy. Finally, we clarified that under this proposed policy, a small group market issuer with off-calendar year coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold) would be considered an exiting issuer and would also be exempt from risk adjustment data validation for the benefit year with the carry-over coverage. Individual market issuers offering or selling any new individual market coverage in the subsequent benefit year would be subject to risk adjustment data

[87] 81 FR 94077.

[88] Further details on the process for how RXCs will be validated during the pilot year will be provided in the 2018 Risk Adjustment Data Validation Protocols that we anticipate will be released in May 2019.

[89] See 83 FR at 16970–16971.

[90] See, *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf; https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RA-Adjustment-Guidance-9–2-15.pdf* and *https://www.regtap.info/uploads/library/DDC_AttestDisc_Slides_050818_v2_5CR_050818(1).pdf.*

[91] 83 FR at 16970 .

[92] 83 FR 16965.

validation, unless another exemption applied.

Comment: Several commenters supported the proposals regarding exiting issuers, indicating that it would not be helpful to market stability and would cause harm to issuers that remain in a market if an exiting issuer that was a negative error rate outlier resulted in adjustments to the risk scores and transfers in the state market risk pool. A few commenters supported the proposal, and some stated that it should be extended so that no issuer's risk score or transfer would be increased for a negative error rate, stating that doing so would create significant uncertainty in financial projections and pricing for issuers.

Response: After consideration of the comments received, we are finalizing the risk adjustment data validation policies regarding exiting issuers, and will apply this policy to the 2018 benefit year risk adjustment data validation and beyond. We believe that the policies on exiting issuers mitigate the impact on remaining issuers, and will aid in the market's stability and proper functioning year to year by limiting the application of an exiting issuer's risk adjustment data validation results to situations where the issuer was overpaid or undercharged for the benefit year being validated. Comments on negative error rates generally (that is, for issuers who are not exiting issuers) are addressed in a separate section of this preamble below.

ii. Risk Adjustment Data Validation Adjustments in Single Issuer Markets

For an issuer that is the sole issuer in a state market risk pool in a benefit year, there are no risk adjustment transfers under the state payment transfer formula and thus, no payment or financial accountability to other issuers for that risk pool.[93] We do not calculate risk adjustment transfers for a benefit year in a state market risk pool in which there is only one issuer, and that issuer is not required to conduct risk adjustment data validation for that state market risk pool.[94] However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer will be subject to risk adjustment data validation for those risk pools with other issuers that had risk adjustment transfers calculated. In addition, the sole issuer may have been identified as an outlier for risk adjustment data validation, and its error rate would be applied to all of its risk adjustment covered plans in the state market risk pools where it was not the sole issuer. Its error rate would also be applied to adjust the subsequent benefit year's transfers for other issuers in the same state market risk pool(s). If the sole issuer that participated in risk adjustment data validation for a benefit year was identified as outlier, and in the following benefit year, a new issuer entered what was formerly the sole issuer risk pool, we proposed that the former sole issuer's error rate would also apply to the risk scores for its risk adjustment covered plans in the subsequent benefit year in the risk pool(s) in which had been the sole issuer—that is, the formerly sole issuer's risk scores and transfer amounts calculated for the benefit year in which a new issuer entered the state market risk pool which did not have risk adjustment transfers calculated in the prior year would be subject to adjustment based on the formerly sole issuer's error rate. In addition, the new issuer would have its risk adjustment transfer adjusted in the current benefit year if the former sole issuer was an outlier with risk score error rates in the prior benefit year's risk adjustment data validation.

Comment: A few commenters disagreed with the proposals for new entrants into a risk pool that formerly was a single issuer risk pool. These commenters stated that all issuers should be treated the same under risk adjustment data validation, and that a new entrant who was not subject to risk adjustment data validation in the year before the year in which it entered the state market risk pool should not be subject to adjustments until both issuers have undergone risk adjustment data validation. One of these commenters also expressed concerns that the proposed policy would create ''perverse incentives'' and decrease market stability, and that issuers would face uncertainty about future liabilities associated with risk adjustment data validation depending on whether another issuer enters the market in question.

Response: After consideration of the comments received, we are finalizing the policies related to the application of risk adjustment data validation results when there are new entrants into a risk pool that formerly was a single issuer risk pool for the 2018 benefit year risk adjustment data validation and beyond. We do not believe that this policy would create perverse incentives, decrease market stability, or cause uncertainty about future liabilities associated with risk adjustment data validation, as this policy results in consistent treatment for all issuers. Thus, transfers will be adjusted for outliers when another issuer joins a sole issuer state market risk pool, as risk adjustment data validation is based on all state markets and outlier status in one market is reflective of outlier status in others.[95] In fact, we believe postponing the application of adjustments due to risk adjustment data validation outlier status for sole issuer state market risk pools until both issuers have undergone risk adjustment data validation possibly could create perverse incentives and result in market distortions, as issuers would not be required to substantiate their EDGE data submissions nor would the issuer identified as an outlier in other market risk pools in the state be subject to the adjustments deemed appropriate through the prior year's risk adjustment data validation. Additionally, we do not agree that issuers would face uncertainty about future liabilities associated with risk adjustment data validation depending on whether another issuer enters the state market risk pool in question. This sole issuer policy finalized in this rule is consistent with the policy established in the 2015 Payment Notice specifying that each issuer's risk score adjustment (from risk adjustment data validation results) will be applied to adjust the plan's average risk score for each of the issuer's risk adjustment covered plans.[96] This policy also aligns with how error rates are applied if a new issuer entered a state market risk pool with more than one issuer.

iii. Risk Adjustment Data Validation and Negative Error Rate Outlier Markets

As discussed in the proposed rule if an issuer is a negative error rate outlier, its risk score will be adjusted upwards. Assuming no changes to risk scores for the other issuers in the state market risk pool, this upward adjustment would reduce the issuer's risk adjustment charge or increase its risk adjustment payment for the applicable benefit year, leading to an increase in risk adjustment charges or a decrease in risk adjustment payments for the other issuers in the state market risk pool. If an issuer is a positive error rate outlier, its risk score will be adjusted downwards. Assuming no changes to risk scores for the other issuers in the state market risk pool, this downward adjustment would increase the issuer's charge or decrease its payment for the applicable benefit year, leading to a decrease in charges or an increase in payments for the other issuers in the state market risk pool. The

[93] See 83 FR at 16967.

[94] Id.

[95] 79 FR 13768 through 13769.

[96] 79 FR 13743 at 13768 through 13769.

intent of this two-sided outlier identification, and the resulting adjustments for outlier issuers that have significantly better than average (negative error rate) and poorer than average (positive error rate) data validation results is to ensure that risk adjustment data validation adjusts risk adjustment transfers for identified, material risk differences between what issuers submitted to their EDGE servers and what was validated in medical records. The increase to risk score(s) for negative error rate outliers is consistent with the upward and downward risk score adjustments that were finalized as part of the original risk adjustment data validation methodology in the 2015 Payment Notice [97] and the HCC failure rate approach to error estimation finalized in the 2019 Payment Notice.[98] That is, the long-standing intent of HHS-operated risk adjustment data validation has been to account for identified risk differences, regardless of the direction of those differences.[99]

However, we sought comment on the impact of the current approach under the error estimation methodology and the outlier adjustment policy for negative error rate outlier issuers, or issuers with significantly lower-than-average HCC failure rates, on other issuers in a state market risk pool, the incentives that negative error rate adjustments may create, and potential modifications to the error rate estimation methodology or the outlier adjustment policy, such as to utilize the state mean failure rate instead of the national mean failure rate, to modify the error rate calculation to the confidence interval instead of the mean, to exclude negative error rate outliers or to use other methods of lessening the impact of negative error rate issuers on affected risk pools, beginning with the 2018 benefit year of risk adjustment data validation or later.

Comment: Some commenters recommended that HHS follow its current risk adjustment data validation methodology and outlier adjustment policy, beginning with the application of 2017 benefit year risk adjustment data validation to 2018 benefit year risk adjustment transfers, without further delay or material change. These commenters stated that further delay of risk adjustment data validation would be unreasonable, create market instability, and would fundamentally jeopardize the program's integrity. These commenters also expressed support for evaluating prospective improvements to the HHS risk adjustment data validation methodology and outlier adjustment policy for future benefit years.

However, other commenters stated that issuers generally did not expect the significant financial impact of risk adjustment data validation to be as large as indicated by the 2016 pilot results that were released by HHS in July 2018,[100] noting that the current risk adjustment data validation error rate methodology was not finalized until April 2018. These commenters also tended to express concern that the error rates are calculated based on adjusting to the mean, instead of the confidence intervals. Some of these commenters were also concerned that issuers may begin booking anticipated impact of risk adjustment data validation on 2018 risk adjustment transfers in their 2019 financials, raising premiums due to the uncertainty associated with estimating those impacts. These commenters believe that the current risk adjustment data validation methodology would lead to higher premiums by compelling issuers to raise premiums to buffer against the potential of unpredictable risk adjustment data validation adjustments, which could create instability and unpredictability in rate setting, and affect market participation.

Several commenters expressed concern about the impact of the negative error rate outliers in cases where the issuer had a zero error rate, particularly given the potential distributive effect of the adjustments to transfers based on market share. Another commenter stated that the exiting issuer proposal on negative error rates should be extended to all issuers such that no issuer's risk score would be increased because of a negative error rate. The commenter believes that this would avoid the creation of significant uncertainty in financial projections and pricing for issuers in the same state market risk pool whose transfers could be negatively affected by another issuer's increased risk score.

One commenter questioned HHS' authority to apply the current risk adjustment data validation error estimation methodology to 2018 risk scores. Another commenter stated its belief that HHS has the authority to make adjustments to the risk adjustment data validation methodology finalized in the 2019 Payment Notice. Some commenters suggested that HHS treat the 2017 benefit year as another pilot year or postpone the implementation of the risk adjustment data validation adjustments to risk scores and transfers until later benefit years (for example, 2020 and beyond).

Many commenters recommended HHS convene a joint industry stakeholder workgroup to develop effective solutions to ensure the risk adjustment program achieves its goals and fulfills its intended purpose. Other commenters recommended broader changes to the risk adjustment data validation process, such as using a targeted data-driven approach to risk adjustment data validation, dividing the audits into individual and small group to separate the impact on transfers, or creating a process to exempt issuers from validating HCCs for which a provider refuses to supply a medical record (when the issuer has demonstrated good faith in trying to obtain that record).

Response: We did not propose and are not making any changes with respect to the application of 2017 benefit year risk adjustment data validation results to 2018 benefit year risk adjustment risk scores and transfers using the current HHS risk adjustment data validation methodology and outlier adjustment policy. HHS conducted 2 pilot years for

[97] For example, we stated in the 2015 Payment Notice that ''the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market''. See 79 FR 13743 at 13769.

[98] For example, in the 2019 Payment Notice, we stated that ''we will use a 1.96 standard deviation cutoff, for a 95 percent confidence interval, to identify outliers'' and that ''when an issuer's HCC group failure rate is an outlier, we will reduce (or increase) each of the applicable initial validation audit sample enrollees' HCC coefficients by the difference between the outlier issuer's failure rate for the HCC group and the weighted mean failure rate for the HCC group.'' We also stated that ''specifically, this will result in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group.'' 83 FR 16930 at 16962. The shorthand ''positive error rate outlier'' captures those issuers whose HCC coefficients are reduced as a result of being identified as an outlier; while the shorthand ''negative error rate outlier'' captures those issuers whose HCC coefficients are increased as a result of being identified as an outlier.

[99] An exception to this approach is the policy finalized, beginning for the 2018 benefit year of risk adjustment data validation, and discussed above in this rule for exiting issuers who are negative error rate outliers.

[100] On July 13, 2018, HHS released a memo via Risk Adjustment Data Validation Audit Tool for issuers titled, ''2016 Benefit Year HHS-operated Risk Adjustment Data Validation (HHS–RADV) Final Results'' that included the program benchmark metrics and the 2016 benefit year HHS–RADV Results Job Aid report that included the HCC group definitions and an illustrative example of the steps for error rate calculation. Thus, issuers were provided with illustrative information on the 2016 benefit year risk adjustment data validation results under the methodology finalized in April 2018, but that information was provided for informational purposes only and should not have been used for purposes of rate setting. In addition, as a second pilot year, the 2016 benefit year risk adjustment data validation results were not applied to adjust risk adjustment transfers.

risk adjustment data validation, and we agree with commenters that another pilot year would not be appropriate at this time (absent the exception for Massachusetts issuers detailed below) because further delay could jeopardize the program's integrity. Thus, we are not making the 2017 benefit year risk adjustment data validation a pilot year, nor are we making any changes to the risk adjustment data validation error estimation methodology for the 2017 or 2018 benefit years.

While the current error estimation methodology was not finalized until April 2018, it was applied prospectively to risk adjustment data validation for the 2017 benefit year. We have also been transparent about the potential for adjustments based on risk adjustment data validation results, including the two-sided nature of such adjustments, since the inception of the program. Consistent with § 153.350(c), as finalized in the final rule Standards Related to Reinsurance, Risk Corridors and Risk Adjustment,[101] HHS may adjust risk adjustment payments and charges to all issuers of risk adjustment covered plans based on adjustments to the average actuarial risk of a risk adjustment covered plan due to errors discovered during data validation. This approach was also reflected in the 2014 Payment Notice, which noted our intent to make adjustments where an issuer under-reported its risk scores.[102] Further, under the original risk adjustment data validation methodology finalized in the 2015 Payment Notice [103], every failure to validate an HCC would have resulted in an adjustment to the issuer's risk score and would have also affected transfers for all issuers in the state market risk pool (including both issuers with HCC validation failures and those without) due to the budget neutral nature of the HHS-operated risk adjustment program.

However, as detailed in the 2019 Payment Notice, we recognized that many issuers would experience some variation and error because providers' documentation of enrollee health status varies across provider types and groups. Our experiences with the Medicare Advantage risk adjustment data validation program and the HHS-operated risk adjustment data validation pilot years reinforced this belief. As a result, to avoid adjusting transfers for any and all failures, we adopted the HCC failure rate methodology, which results in adjustments to an issuer's risk score only when the issuer's failure rate is statistically different from the weighted mean failure rate, or total failure rate, for all issuers that submitted initial validation audits (that is, the issuer is identified as an outlier). Similar to the original methodology finalized in the 2015 Payment Notice, when there is an outlier issuer, the transfers for other issuers in the state market risk pool will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program. We further note that, based on our analysis of the 2016 benefit year risk adjustment data validation results and our analysis of the initial estimated 2017 benefit year risk adjustment data validation results, we have found that the HCC failure rate approach to error estimation significantly reduces the overall transfer impact of adjustments when compared with results under the original methodology.

Additionally, as detailed above, the identification of positive and negative error rate outliers and the resulting adjustments under the HCC failure rate methodology is consistent with the two-sided adjustment approach adopted under the original risk adjustment methodology finalized in the 2015 Payment Notice. Except as provided elsewhere in this final rule for negative error rate outliers resulting from exiting issuers, we continue to believe that adjusting for both negative and positive error rate outliers ensures that issuers' actual actuarial risk is reflected and that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. It also incentivizes issuers to achieve the most accurate EDGE data submissions for initial risk adjustment transfer calculations. For all these reasons, we do not believe that further changes are needed to the error estimation methodology or the outlier adjustment policy at this time. We will apply the current methodology and outlier adjustment policy to both the 2017 benefit year and 2018 benefit year of risk adjustment data validation. We intend to solicit further comments and work with stakeholders regarding potential changes for future benefit years.

However, as explained above, while issuers have been on notice since 2012 that adjustments based on risk adjustment data validation results could occur,[104] we recognize that the initial experience during the pilot years of risk adjustment data validation has caused concern over the potential direction and magnitude of the adjustments. After consideration of the comments received, and further analysis of timing considerations (such as the impact on adjustments of any successful risk adjustment data validation appeals, as well as the proposed change to the risk adjustment appeals holdback for the 2018 benefit year and beyond (''Proposed Holdback Guidance'' [105])), we are updating the timeline for publication, collection, and distribution of risk adjustment data validation adjustments to transfers. We still intend to publish 2017 benefit year error rates in May 2019, but under our updated timeline, we intend to publish the 2017 benefit year risk adjustment data validation adjustments on August 1, 2019 after the release of the Summary Report on Permanent Risk Adjustment Transfers for the 2018 Benefit Year (intended to be released on June 28, 2019). The information released in the August 1, 2019 report on risk adjustment data validation adjustments to transfers will be based on the preliminary 2017 benefit year risk adjustment data validation results, prior to the resolution of appeals. The August 1, 2019 report will also include information on 2017 benefit year default data validation charges under § 153.630(b)(10) and allocation of those amounts. We will also delay the collection and distribution of 2017 benefit year risk adjustment data validation adjustments to 2018 benefit year risk adjustment transfers and 2017 benefit year default data validation charges and allocations until 2021 to provide issuers with more options on how and when to book financial impacts from risk adjustment data validation, in keeping with guidance from state departments of insurance, where applicable. Specifically, we intend to update the Medical Loss Ratio Form Instructions to provide guidance to issuers, consistent with § 153.710(g)(2) and (3), regarding the reporting of risk adjustment data validation adjustments for medical loss ratio reporting purposes. The guidance would instruct issuers to report risk adjustment data validation adjustments and default data validation charges and allocations in the same medical loss

[101] 77 FR 17234.

[102] 78 FR at 15438.

[103] For example, we stated in the 2015 Payment Notice that ''the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market''. See 79 FR 13769.

[104] See, Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 FR 17234, 2014 Payment Notice, 78 FR at 15438, and 2015 Payment Notice, 79 FR 13769.

[105] Available at *www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Proposed-Changes-RA-Holdback-2018BY.pdf*.

ratio reporting year as the year when these amounts are collected and disbursed (for example, the 2017 benefit year risk adjustment data validation adjustments and default data validation charges and allocations would be reported in the 2021 MLR reporting year). We also intend to update the Unified Rate Review Template (URRT) instructions to permit issuers and states to consider risk adjustment data validation adjustment impacts in rates for the year when these amounts will be collected and disbursed (for example, issuers and states would have the option to consider 2017 benefit year risk adjustment data validation adjustments in rate setting for the 2021 benefit year, instead of 2020 benefit year rate setting). Changing the timeline for the year in which issuers may pay, receive, and account for their results from risk adjustment data validation in the MLR and URRT submissions will only change the timing. This approach will not change the associated processes and therefore will not increase burden on issuers or states. Delaying the collection and distribution of 2017 benefit year risk adjustment data validation adjustments to 2018 benefit year risk adjustment transfers until 2021 will also allow more time for HHS to work with issuers to resolve any risk adjustment data validation appeals. It will also help mitigate the potential for additional uncertainty and instability that could be created by making adjustments before appeals are resolved, as a successful risk adjustment data validation appeal could affect the calculated risk score error rate and accompanying adjustments to transfers.

We anticipate adhering to a similar timeline in future years for the collection and payment of risk adjustment data validation adjustments to risk adjustment transfers (along with default data validation charges and allocations), such that risk adjustment transfers without risk adjustment data validation adjustments would be reported by June 30th of the year after the applicable benefit year, and issuers would report those amounts in the medical loss ratio reports submitted by July 31st of the year after the applicable benefit year. The preliminary risk adjustment data validation adjustments that could impact that benefit year's transfers, along with information on default data validation charges and allocations for the applicable benefit year, would be reported after the June 30 report is published, and we would collect and disburse risk adjustment data validation adjustments and default data validation charges and allocations two years after the announcement. Issuers would be instructed to reflect those final adjustment amounts and default data validation charges and allocations in the medical loss ratio reporting year in which collections and payments of those amounts occur, and would be permitted to reflect those amounts in rate setting for that same benefit year. For example, 2018 benefit year risk adjustment data validation adjustments and default data validation charges and allocations would be collected and paid in 2022; issuers could account for the impacts of those amounts in rate setting for the 2022 benefit year, and issuers would report the adjustments and default data validation charges and allocations in the 2022 benefit year medical loss ratio reporting year. Furthermore, given these timeline changes for collecting and paying risk adjustment data validation adjustments being finalized in this final rule and in response to comments that we received indicating that some issuers had difficulty obtaining medical records, we are also considering options to extend the timeline for conducting and completing the risk adjustment data validation processes for issuers and HHS. We believe that this additional time may help issuers in completing the operational processes in future benefit years. Therefore, we intend to seek input on an updated risk adjustment data validation timeline beginning with the 2018 benefit year to provide more time for medical record collection during the initial validation audits and more time for the completion of the second validation audit.

Comment: Some commenters supported the current policy that involves adjusting for both positive and negative outliers with one of these commenters noting that adjustments for negative outliers encourage complete and accurate coding, and more comprehensive documentation. Many commenters, on the other hand, supported the elimination of risk score adjustments for issuers that are negative error rate outliers, noting that a negative error rate issuer should not be rewarded for submitting incorrect or incomplete data to the EDGE server and that negative error rate outliers create uncertainty in the market, particularly for issuers within the confidence bounds (that is, those issuers who are not outliers). One commenter supported adjusting an issuer's risk score when the issuer's error rate materially deviates from a statistically meaningful value or when its error rate materially deviates from a statistically meaningful value by a multiplier figure that values back to the outlier cutoff point. Another commenter recommended that HHS apply the error rates to the transfers of the benefit year that is being audited, rather than to transfers in the following benefit year.

Several commenters recommended that outlier issuers' error rates be calculated based on the ends of the confidence interval instead of the mean to eliminate the ''payment cliff'' under the current methodology. Some of these commenters preferred adjusting outliers to the nearest ends of the confidence intervals as a short term solution to reduce the negative financial impact on other issuers in the state market risk pool because, for example, they believe the nationwide weighted average provides an adjustment that is too large in states where the statewide group failure rate is lower than the nationwide average. Some of these commenters also noted that adjusting to the confidence intervals would minimize unexpected impacts on transfers and remove the extreme impact of small adjustments in HCC accuracy for issuers whose failure rates are near the edges of the confidence interval.

Response: We did not propose and are not making any changes to the error estimation methodology applicable to 2017 and 2018 benefit years risk adjustment data validation. We have concerns about adjusting outlier issuers to the edges of the confidence intervals instead of the mean, which is why that approach was not adopted in the current error estimation methodology. Specifically, we are concerned that adjusting to the edges of confidence intervals may effectively reduce the impact of risk adjustment data validation results to the point that the positive error rate outlier adjustments may not provide enough disincentive to prevent inappropriate coding and the benefit of upcoding may outweigh the potential costs of the risk adjustment data validation risk score adjustments. However, in future years, after we have analyzed more data on the risk adjustment data validation results, we intend to consider refinements to the risk adjustment data validation process and methodology, and may consider alternative options for error rate adjustments, such as using multiple or smoothed confidence intervals for outlier identification and risk score adjustment. While we are interested in applying the risk adjustment data validation results to the benefit year being audited, we have concerns that in order to switch to that policy starting with the 2018 benefit year, we would be adjusting 2018 benefit year risk adjustment twice (once for the 2017

benefit year risk adjustment data validation results and a second time for the 2018 benefit year risk adjustment data validation results). However, we will continue to consider modifications to risk adjustment data validation processes and methodologies, including which benefit year transfers' the data validation adjustments are applied to, for future benefit years. As mentioned elsewhere in this final rule, we intend to consider the comments received for potential updates to the current methodology and outlier adjustment policy for future benefit years. We will consult with stakeholders before implementing any such changes.

Comment: One commenter requested that HHS treat the 2017 benefit year as a pilot year for Massachusetts for risk adjustment data validation purposes since the 2017 benefit year was the first year that Massachusetts issuers participated in the HHS-operated risk adjustment program. This commenter noted that there will be some distortion in the results of audits for issuers in Massachusetts, and was especially concerned that this distortion may be magnified for smaller issuers.

Response: We understand that Massachusetts issuers are in a unique situation with regard to risk adjustment data validation for the 2017 benefit year, since the 2017 benefit year was the first year in which Massachusetts participated in the HHS-operated risk adjustment program and submitted data to EDGE servers, and no Massachusetts issuers [106] had an opportunity to participate in the pilot years of HHS risk adjustment data validation. Therefore, in response to comments and after consideration of the specific facts and circumstances involved, we believe that exercising our enforcement discretion to provide Massachusetts issuers with a non-adjustment year for risk adjustment data validation is appropriate. It is consistent with our general approach to implementing risk adjustment data validation in other states where HHS is responsible for operating the program and we will therefore exercise our discretion to operate risk adjustment data validation for the 2017 benefit year as a pilot year for Massachusetts.

Massachusetts issuers will receive 2017 benefit year risk adjustment data validation error rate results, but these issuers will not have their 2018 benefit year risk adjustment risk scores or transfers for Massachusetts state market risk pools adjusted based on 2017 risk adjustment data validation results. Furthermore, Massachusetts issuers' failure rates will not be included in the calculation of the national metrics for the 2017 benefit year risk adjustment data validation to avoid the potential distortion in the national metrics that will be applied to issuers in other state market risk pools. All other issuers in all other states and the District of Columbia will have their 2018 benefit year risk adjustment risk scores and transfers adjusted based on 2017 benefit year risk adjustment data validation results in accordance the current error estimation methodology finalized in the 2019 Payment Notice. In addition, to the extent that a Massachusetts issuer also offered risk adjustment covered plans in other state market risk pools, its 2018 benefit year risk adjustment risk scores and transfers for those other state market risk pools will be adjusted based on 2017 benefit year risk adjustment data validation results.

h. Exemptions From Risk Adjustment Data Validation

In previous rules,[107] we established exemptions from the HHS-operated risk adjustment data validation requirements for issuers with 500 or fewer billable member months statewide and issuers at or below a materiality threshold for the benefit year being audited. Additionally, on April 9, 2018, we released guidance indicating that we intended to propose a similar exemption from risk adjustment data validation requirements for certain issuers in or entering liquidation.[108] The purpose of these policies is to address numerous concerns, particularly from smaller issuers and state regulators, regarding the regulatory burden and costs associated with complying with the HHS-operated risk adjustment data validation program. HHS previously considered these concerns and provided relief where possible, and under this final rule, we are codifying these exemptions in regulation at § 153.630(g), as described further below.

In the 2019 Payment Notice, we finalized that beginning with 2017 benefit year HHS-operated risk adjustment data validation, issuers with 500 billable member months or fewer statewide in the benefit year being audited that elect to establish and submit data to an EDGE server will not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results.[109] We explained that exempting these issuers from the requirement to hire an initial validation auditor is appropriate because they will have a disproportionately high operational burden for compliance with risk adjustment data validation. We noted that, beginning with 2018 benefit year risk adjustment data validation, these issuers will not be subject to random (or targeted) sampling under the materiality threshold, and they will continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. Issuers who qualify for this exemption will not be subject to enforcement action for non-compliance with risk adjustment data validation requirements, or be assessed the default data validation charge under § 153.630(b)(10). We stated that the determination of whether an issuer has 500 or fewer billable member months will be made on a statewide basis (that is, by combining an issuer's enrollment in a state's individual, small group, and merged markets, as applicable, in a benefit year). In the proposed rule, we proposed to codify this exemption at § 153.630(g)(1). We received no comments on codifying this exemption; therefore, in this final rule, we are codifying this exemption as proposed. Consistent with the finalized policy adopted in the 2019 Payment Notice, this exemption is available beginning with the 2017 benefit year of risk adjustment data validation.

Second, in the 2018 Payment Notice, HHS finalized a materiality threshold for risk adjustment data validation to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans.[110] We evaluated the burden associated with risk adjustment data validation, particularly, the fixed costs associated with hiring an initial validation auditor and submitting results to HHS on an annual basis. We established a materiality threshold for risk adjustment data validation that considered the burden of such a process on smaller plans. Specifically, we stated that issuers with total annual premiums at or below $15 million for risk adjustment covered plans (calculated statewide based on the premiums of the benefit year being validated) will not be subject

[106] Participation in risk adjustment data validation is based on HIOS IDs and not parent companies. Therefore, while some issuers' parent companies in Massachusetts may have previously participated in the HHS-operated risk adjustment program in other states under other issuer HIOS IDs, no issuer HIOS IDs in Massachusetts previously participated in the HHS-operated risk adjustment program, including the pilot years of risk adjustment data validation.

[107] See 81 FR 94058 at 94104 and 83 FR 16930 at 16966.

[108] Exemption from HHS-Operated Risk Adjustment Data Validation (HHS–RADV) for Issuers in Liquidation or Entering Liquidation (April 9, 2018). *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf.*

[109] 83 FR 16930 at 16966.

[110] 81 FR 94058 at 94104–94105.

to the annual initial validation audit requirements, but will still be subject to an initial validation audit approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent audits). Under the established process, we will conduct random and targeted sampling for issuers at or below the materiality threshold, beginning with the 2018 benefit year of risk adjustment data validation. Even if an issuer is exempt from initial validation audit requirements under the materiality threshold, HHS may require these issuers to make records available for review or to comply with an audit by the federal government under § 153.620.

We proposed to codify the materiality threshold exemption at § 153.630(g)(2), providing that an issuer of a risk adjustment covered plan would be exempt from the data validation requirements in § 153.630(b) if the issuer is at or below the materiality threshold defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under a random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent participation in risk adjustment data validation).[111]

Consistent with the materiality threshold finalized in the 2019 Payment Notice,[112] we proposed to define the materiality threshold as total annual premiums at or below $15 million, based on the premiums of the benefit year being validated for all of the issuer's risk adjustment covered plans in the individual, small group, and merged markets (as applicable) in the state. We did not propose any trending adjustment to the materiality threshold, but stated that if we were to modify the definition of materiality to trend the $15 million threshold in future benefit years, we would propose that change through notice-and-comment rulemaking.

We noted that if an issuer of a risk adjustment covered plan within the materiality threshold is not exempt from the data validation requirements for a given benefit year (that is, the issuer is selected by random and targeted sampling), and fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, the issuer would be subject to a default data validation charge in accordance with § 153.630(b)(10), and may be subject to other enforcement action.

We are codifying this exemption at § 153.630(g)(2), including the establishment of a $15 million threshold that will continue to apply until such time as it may be changed through notice-and-comment rulemaking as proposed. Consistent with the original policy finalized in the 2018 Payment Notice, this exemption is available beginning with 2018 benefit year risk adjustment data validation.

Lastly, as noted in this rule, HHS released guidance on April 9, 2018 indicating our intention to propose in future rulemaking an exemption from risk adjustment data validation requirements for certain issuers in liquidation or that will enter liquidation. The purpose of exempting these issuers is similar to the reasons outlined in this rule for smaller issuers and those below the materiality threshold—to recognize the burdens and costs associated with the risk adjustment data validation requirements on these issuers, given their reduced financial and staff resources. Under this proposal, certain issuers in liquidation or that will enter liquidation would be exempt from the requirement to hire an initial validation auditor and submit initial validation audit results, as well as the second validation audit requirements, and would not be subject to enforcement action for non-compliance with risk adjustment data validation requirements or be assessed the default data validation charge under § 153.630(b)(10).

We proposed codifying at § 153.630(g)(3) that an issuer would be exempt from the applicable benefit year of risk adjustment data validation if the issuer is in liquidation as of April 30th of the year when transfer adjustments based on data validation results are made (that is, 2 benefit years after the benefit year being audited). For the 2018 benefit year and beyond, we proposed that to qualify for the exemption, the issuer must also not be a positive error rate outlier in the prior benefit year of risk adjustment data validation (that is, the issuer is not a positive error rate outlier under the error estimation methodology in the prior year's risk adjustment data validation) as outlined in proposed paragraph (g)(3)(ii). If an issuer in liquidation or that will enter liquidation by the applicable date was a positive error rate outlier in the previous year's risk adjustment data validation, we proposed not to exempt the issuer from the subsequent benefit year's risk adjustment data validation, and the issuer would be required to participate in risk adjustment data validation or receive the default data validation charge in accordance with § 153.630(b)(10) unless another exemption applies.

To qualify for this exemption in any year, we proposed under paragraph (g)(3)(i) that the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer is in or will enter liquidation no later than April 30th 2 years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer. In proposed paragraph (g)(3)(iii), we proposed to define liquidation as meaning that a state court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest. Our intention with this policy was to align the definition of liquidation with state law on liquidation of health insurance issuers and the National Association of Insurance Commissioners' Model Act on receivership where possible.[113]

While we understood the exact date of a liquidation order may be uncertain in specific circumstances, we proposed that the individual signing the attestation must be reasonably certain that the issuer will enter liquidation by April 30th 2 benefit years after the benefit year being audited.

Under our proposal, we would accept an attestation from a representative of the state's department of insurance, an appointed liquidator, or other appropriate individual who can legally and financially bind the issuer. HHS would verify the issuers' liquidation status with the applicable state regulators for issuers who submitted an attestation under § 153.630(g)(3). We also proposed that, because the April 30th 2 benefit years after the benefit year being audited is after the deadline for completing the initial validation audit for a given benefit year, an issuer who submits an attestation for this exemption but is determined by HHS to not meet the criteria for the exemption would receive a default data validation charge in accordance with § 153.630(b)(10) if the issuer fails to complete or comply with the risk adjustment data validation process within the established timeframes for

[111] When selecting issuers at or below the materiality threshold for more frequent initial validation audits, we will consider the issuer's prior risk adjustment data validation results and any material changes in risk adjustment data submissions, as measured by our quality metrics. See 81 FR 94105.

[112] See 83 FR 16966.

[113] National Association of Insurance Commissioners Model Act, Issuer Receivership Act. 2007. *http://www.naic.org/store/free/MDL-555.pdf.*

the given benefit year, unless another exemption applies.

Additionally, we noted that any issuer that qualifies for any of the three exemptions in proposed § 153.630(g) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, but that issuer's risk score and its associated risk adjustment transfers could be adjusted if other issuers in that state market risk pool were outliers and received risk score error rates for that benefit year's risk adjustment data validation.

We are also finalizing the codification of the liquidation exemption at § 153.730(g)(3) as proposed for the 2018 benefit year. For 2017 benefit year risk adjustment data validation, we intend to work with issuers in liquidation and will exercise our enforcement discretion, where appropriate, to provide relief consistent with the criteria outlined in the April 9, 2018 guidance [114] and the proposed rule.

Comment: Commenters generally supported the codification of a materiality exemption, but some suggested a different threshold, noting a flat materiality threshold would not account for variations across markets. Some of these commenters suggested a threshold based on a percentage of premiums (for example, issuers whose premiums account for less than 5 percent of the statewide premium). Alternatively, some commenters stated that if a flat materiality threshold is used, it should be updated in future benefit years to account for changes in market conditions. One commenter did not support the establishment of a materiality threshold that would exempt issuers from conducting risk adjustment data validation each year. This commenter stated that all issuers should be subject to the same requirements and operate on a level playing field, and if all issuers participate in risk adjustment data validation, all issuers will have audited results, which will promote overall confidence in the risk adjustment program.

Response: Although we appreciate the comments, as noted in the proposed rule, we proposed to codify the materiality exemption that was finalized in the 2018 and 2019 Payment Notices. As detailed in these prior rulemakings [115], we believe this exemption is appropriate because the fixed costs associated with hiring an initial validation auditor and submitting results to HHS may be disproportionately high for smaller issuers, and may even constitute a large portion of their administrative costs. Also, we estimated that issuers that cover under 2 percent of membership nationally would qualify for this exemption, so the effect of the exemption on risk adjustment data validation is not material. HHS will continue to review and analyze whether the threshold should be updated for future benefit years, but we are maintaining the current $15 million threshold because we believe that, under current market conditions, it still delineates properly the limited group of smaller issuers of risk adjustment covered plans that is appropriate for the exemption's relief. As detailed in prior rulemakings that established this exemption, issuers who meet the materiality threshold would not be exempt from conducting risk adjustment data validation each year. Issuers meeting this exemption will be subject to random and targeted sampling to participate in risk adjustment data validation approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent participation in risk adjustment data validation), beginning with the 2018 benefit year of risk adjustment data validation. We agree with the commenter that issuers should generally be subject to the same requirements for risk adjustment data validation, but also believe there are limited exemptions that may be appropriate to address specific concerns. We believe that, for the reasons articulated above, there is adequate justification for the materiality threshold as currently structured. We are therefore finalizing the codification of the materiality threshold exemption at § 153.630(g)(2).

Comment: Commenters disagreed with the proposal to exempt certain liquidating issuers from the requirements to hire an initial validation auditor, submit initial validation audit results, and undergo the second validation audit, and from enforcement actions for non-compliance with risk adjustment data validation requirements, including the default data validation charge. One commenter stated that issuers facing liquidation might have incentives to submit inaccurate risk adjustment data given their financial pressures, and that requiring these issuers to participate in risk adjustment data validation will promote confidence in the program and the quality of the data submitted by these issuers. Two commenters had significant concerns that some plans might find ways to take advantage of the exemption without entering liquidation. Also, in order to create a level playing field for all issuers of risk adjustment covered plans, one commenter stressed the importance of requiring all issuers to conduct risk adjustment data validation each year, since this will promote confidence in the transfers by ensuring the quality and integrity of the issuer data.

Response: While we recognize the commenters' concern that an issuer that anticipates entering liquidation may have an incentive to provide poor quality risk adjustment data, we require all issuers to attest to the accuracy, quantity and quality of their risk adjustment data after the applicable benefit year's data submission deadline during the EDGE Attestation and Discrepancy Reporting Process, and part of this attestation notes that issuers who submit false data upon which risk adjustment transfers are calculated could be subject to prosecution under the False Claims Act. HHS also has additional safeguards that help mitigate the possibility that issuers will provide poor quality data in connection with the risk adjustment program, including authority to impose a civil monetary penalty for failure to comply with risk adjustment data requirements, as well as to impose a risk adjustment default charge where an issuer failed the EDGE quality/quantity evaluation by submitting inadequate data.[116] Further, the requirements that the attesting individual be reasonably certain that the issuer will enter liquidation and that, beginning with the 2018 benefit year, an issuer cannot be a positive error rate outlier in risk adjustment data validation for the prior benefit year are further safeguards intended to help protect against inappropriate use of the liquidation exemption. We also note that if an issuer does not enter liquidation by the applicable April 30th due date, this exemption would not be available and the issuer would be subject to a default data validation charge under § 153.630(b)(10). Therefore, we do not anticipate that issuers will inappropriately attempt to claim the exemption without entering liquidation, and have put safeguards in place to protect against situations where an issuer attempts to do so. Since the liquidation exemption is consistent with our broader policy of providing relief where appropriate to issuers with limited resources, and the concerns noted by the commenters should be ameliorated by the safeguards and

[114] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf.*

[115] See 81 FR 94104 through 94105 and 83 FR 16966 through 16967.

[116] See § 153.740(a) and (b).

enforcement authorities described above, we are finalizing the liquidation exemption for the 2018 benefit year as proposed. We intend to work with issuers who meet the criteria outlined in the April 9, 2018 guidance [117] and the proposed rule and will use enforcement discretion, where appropriate, to exempt these issuers for 2017 benefit year risk adjustment data validation.

E. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Definitions (§ 155.20)

We proposed to amend § 155.20 to add definitions of ''direct enrollment technology provider,'' ''direct enrollment entity,'' ''direct enrollment entity application assister,'' and ''web-broker.'' After consideration of the comments received, we are finalizing the adoption of these new definitions as proposed. For further discussion, please see the preamble to §§ 155.220, 155.221, and 155.415.

Comment: Several commenters supported the proposed definitions, in particular the distinction created between ''direct enrollment technology provider'' and ''web-broker.'' One commenter recommended the term ''direct enrollment technology provider'' not be included in the definition of ''web-broker'' to avoid potential confusion that direct enrollment technology providers are licensed as brokers. However, the same commenter agreed that direct enrollment technology providers and web-brokers should be subject to the same requirements and acknowledged the increased complexity of completely distinguishing them.

Response: ''Direct enrollment technology provider'' is defined as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221. This definition refers to these entities as a type of web-broker business entity, and the accompanying definition of ''web-broker'' similarly includes a reference to direct enrollment technology providers, for the purpose of generally extending the same requirements to direct enrollment technology providers as web-brokers, unless otherwise specified. The creation of the term ''direct enrollment technology provider'' and its accompanying definition was necessary to distinguish these entities from other types of web-brokers, where appropriate. See the below preamble discussion in §§ 155.220 and 155.221 for further details.

2. General Functions of an Exchange

a. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline to respond to requests for assistance. In the 2017 Payment Notice, we explained the distinction between a toll-free call center and a toll-free hotline, for purposes of specifying the different requirements for SBE–FPs and other Exchanges.[118] In the 2019 Payment Notice, we finalized regulations providing for a leaner FF–SHOP implementation, and have adopted that approach. In that rulemaking, we explained that the FF–SHOPs will continue to provide a call center to answer questions related to the SHOP.[119] Currently, employers purchase and enroll their employees in new FF–SHOP coverage through issuers and through agents and brokers registered with the FFE, and no longer enroll in SHOP coverage using an online FF–SHOP platform.

Under this approach, FF–SHOP call center volume has been extremely low. Given this experience, we proposed to amend § 155.205(a) to allow SHOPs operating in the leaner fashion described in the 2019 Payment Notice to operate a toll-free telephone hotline, as required by section 1311(d)(4)(B) of the PPACA, and to eliminate the requirement to operate a more robust call center. We proposed to amend the interpretation provided in the 2017 Payment Notice of what is required to establish a toll-free hotline, as required by section 1311(d)(4)(B) of the PPACA. There, we stated that a toll-free hotline includes the capability to provide information to consumers and appropriately direct consumers to the federally operated call center or HealthCare.gov to apply for, and enroll in, coverage through the Exchange. Given that SHOPs that operate in the leaner fashion no longer offer online enrollment and to reflect the option for such SHOPs to provide a toll-free hotline, rather than a more robust call center, we proposed that a toll-free hotline include the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

The toll-free hotline provided by such SHOPs would consist of a toll-free number linked to interactive voice response capability, with prompts to pre-recorded responses to frequently asked questions, information about locating an agent and broker in the caller's area, and the ability for the caller to leave a message regarding any additional information needed. We stated our belief that this hotline would adequately address the needs of potential FF–SHOP consumers requesting assistance, and appropriately direct consumers to services to apply for, and enroll in, FF–SHOP coverage.

Comment: A few commenters were in support of operating the call center in a leaner fashion. One commenter was not in support of the proposal, concerned that consumers would not be able to obtain timely assistance.

Response: The SHOP toll-free call center will continue to provide timely access to assistance. Consumers can immediately access pre-recorded responses to frequently asked questions along with information about locating an agent and broker in the consumer's area. Further, the consumer can leave a message or send an email requesting any further information needed, which will be monitored daily for prompt response. Therefore, we are finalizing these changes as proposed.

b. Navigator Program Standards (§ 155.210)

Section 1311(d)(4)(K) and 1311(i) of the PPACA require each Exchange to establish a Navigator program under which it awards grants to entities to conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs, and the availability of premium tax credits, and cost-sharing reductions; facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the

[117] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf.*

[118] 81 FR at 12246.

[119] 83 FR at 16997.

statutorily required Navigator duties through regulations at § 155.210 (for all Exchanges) and § 155.215 (for Navigators in FFEs).

Further, section 1311(i)(4) of the PPACA requires the Secretary to establish standards for Navigators to ensure that Navigators are qualified, and licensed, if appropriate, to engage in the Navigator activities described in the statute. This provision has been implemented at § 155.210(b) (for all Exchanges) and at § 155.215(b) (for Navigators in FFEs).

Section 155.210(e)(9) specifies that an Exchange may require or authorize Navigators to provide assistance with a number of topics not specifically mentioned in the statute, including certain post-enrollment activities. This section specifies that Navigators operating in FFEs are authorized to provide assistance on these topics and are required to do so under Navigator grants awarded in 2018 or later.[120] To provide more flexibility related to the required duties for Navigators operating in FFEs, we proposed to amend § 155.210(e)(9) to make assistance with these topics permissible for FFE Navigators, not required, effective upon the awarding of the FEE navigator grants in 2019. We stated our belief that making assistance with these topics optional for FFE Navigators would reduce regulatory burden on FFE Navigator entities and better meet consumers' needs by allowing FFE Navigators to prioritize work according to consumer demand, community needs, and organizational resources.

We acknowledge that HHS added these duties 2 years ago to ensure the availability of more robust consumer assistance; however, since that time, there have been programmatic and health care coverage policy changes that have caused us to reflect further. We stated our belief that consumers would be better served by allowing more flexibility for Navigators to tailor their services to make the most of their resources and to fit the needs of their communities.

In the proposed rule, we emphasized that FFE Navigators would be authorized to continue to provide assistance with any of the topics listed under § 155.210(e)(9). Under the proposed approach, if FFE Navigator grantees choose to provide any of the assistance specified in § 155.210(e)(9), we will continue to expect them to assess their communities' needs and build competency in the assistance activities in which they are engaging. It is important to note that the current FFE Navigator training for annual certification or recertification might continue to include training on some of the § 155.210(e)(9) topics. To supplement the required FFE Navigator training, we also plan to continue providing FFE Navigators with additional information related to these assistance activities through informal webinars, newsletters, and technical assistance resources such as fact sheets and slide presentations. FFE Navigator grantees that opt to carry out any of the assistance activities in § 155.210(e)(9) will be expected to draw upon these materials to ensure their staff and volunteers are adequately prepared to provide that assistance. Our proposal also retained SBE autonomy to determine whether requiring or authorizing the SBE's Navigators to perform the activities listed in § 155.210(e)(9) best meets the state's needs and resources.

We recognize that the time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies.

To better understand the future impact of removing this requirement, we requested comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities described at § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also requested comment on how FFE Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9).

In addition to proposing to increase FFE Navigator flexibility with regard to the types of assistance they provide, we also proposed to provide more flexibility related to the training requirements that Exchanges establish for Navigators. Sections 155.210(b)(2) and 155.215(b)(2) establish Navigator training standards consistent with section 1311(i)(4) of the PPACA. Section 155.210(b)(2) specifies that Exchanges must develop and publicly disseminate a set of training standards to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure expertise in several specific topic areas.[121] Currently, under § 155.210(b)(2), Exchanges (including SBEs) that opt to require their Navigators to perform the assistance described in § 155.210(e)(9) must also develop and disseminate training standards related to the specific assistance areas they require under § 155.210(e)(9). Also, Navigators in FFEs currently must be trained in fifteen additional topic areas identified at § 155.215(b)(2).[122]

To provide more flexibility related to the training requirements for Navigators, we proposed to streamline both the requirement in § 155.210(b)(2) for all Exchanges to develop and disseminate Navigator training standards on specific topics, and the list of required training topics for FFE Navigators in § 155.215(b)(2). We proposed to amend the requirement at § 155.210(b)(2) to require Exchanges to develop and publicly disseminate training standards to ensure that the entities and individuals are qualified to engage in Navigator activities, including in the four major areas currently specified at § 155.210(b)(2)(i) through (iv). This would eliminate the training requirements at current § 155.210(b)(2)(v)–(ix) that correspond to the activities outlined in § 155.210(e)(9), since those activities would no longer be required. We also proposed to replace the current list of fifteen additional FFE Navigator training topics at § 155.215(b)(2) with a cross-reference to the amended § 155.210(b)(2) topics.[123] In the proposed rule, we

[120] These topics are: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; the Exchange-related components of the premium tax credit reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and, referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

[121] These areas include: the needs of underserved and vulnerable populations; eligibility and enrollment rules and procedures; the range of QHP options and insurance affordability programs; and, the privacy and security standards applicable under § 155.260.

[122] These areas include: information on QHPs, including benefits covered, differences among plans, payment process, rights and processes for appeals and grievances, and contacting individual plans; the tax implications of enrollment decisions; information on affordability programs; Exchange eligibility and enrollment rules and procedures; privacy and security standards, customer service standards; outreach and education methods and strategies; appropriate contact information for other agencies for consumers seeking information about coverage options not offered through the Exchange; basic concepts about health insurance and the Exchange; working effectively with individuals with limited English proficiency, and disabled, rural, underserved or vulnerable individuals; providing linguistically and culturally appropriate services; ensuring physical and other accessibility for people with a full range of disabilities; and applicable administrative rules, processes and systems related to Exchanges and QHPs.

[123] We note that § 155.215 also applies to non-Navigator assistance personnel, also referred to as

stated that we believe the revised regulations would be broad enough to ensure that each Navigator program fulfills the requirements described in section 1311(i) of the PPACA.

This approach would provide Exchanges greater flexibility in designing their Navigator training programs to ensure coverage of the most instructive and timely topics and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their required duties. This additional flexibility would also allow Exchanges to focus on training areas they determine to be most relevant to the populations they serve and on the policy and operations of the Exchange in which they operate.

Furthermore, Exchanges could opt to provide more training than would be required under these proposed amendments. For example, in addition to the FFE annual Navigator training, required for Navigator certification under § 155.215(b), Navigators in FFEs are provided with training throughout the year that serves as a supplement to the annual FFE Navigator training by covering timely and appropriate training topics that might not be included in the annual FFE Navigator training. This additional training provided by FFEs, is consistent with the requirement that FFE Navigators obtain continuing education, as specified at § 155.215(b)(1)(iv), and we intend to continue this practice.

Currently, HHS provides SBEs, including SBE–FPs, the flexibility to decide whether they will require or authorize their Navigators to provide assistance on any or all of the areas described at § 155.210(e)(9). The changes that we are finalizing in this final rule do not change that flexibility. If SBEs choose to authorize or require their Navigators to provide assistance in any of the areas listed at § 155.210(e)(9), they will still be required to ensure that their Navigators are qualified to provide this assistance.

Under our amendments, any SBEs opting to authorize or require their Navigators to provide any or all of the types of assistance listed at § 155.210(e)(9) will have the flexibility to determine effective approaches to training their Navigators on performing these types of assistance based on local experience. We believe each Exchange is best positioned to determine the training that is most appropriate for the activities of their Navigators.

These proposals are intended to increase program flexibility within Exchanges and decrease regulatory burden related to Navigator training while maintaining standards that will ensure that Navigators are sufficiently prepared to carry out all required or authorized activities. We solicited comments on these proposals and received a range of comments in favor and not in favor of finalizing this policy. Streamlining the Navigator training requirements will allow Exchanges and Navigators to prioritize their training resources on those tasks that will best serve their state markets and Exchanges. HHS will continue to provide training on all current Navigator training topics. The format of the provided training may include other methods of technical assistance, but HHS is still committed to providing training on all of the streamlined Navigator training topics. We are finalizing these changes as proposed.

Finally, we proposed allowing, but not requiring, Navigators to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. We are not finalizing this proposal. For further discussion of that proposal, please see the preamble to § 155.220.

Comment: We received some comments in support of the state flexibility the rule grants to SBEs to design their own training requirements. However, many commenters expressed concern about this proposal, citing the complexity of the enrollment process; the need to educate assisters on how to best serve underserved and vulnerable populations; the need to train Navigators on how to provide culturally and linguistically appropriate services; and the unique role Navigators play in helping underserved and vulnerable populations to both enroll in and use their coverage. Commenters also stated that reducing the number of mandatory training requirements may result in Navigators not being fully equipped to serve underserved and vulnerable consumers.

Response: We agree with the commenters that supported the enhanced flexibility that the rule grants to SBEs to design the training requirements that are the best fit for their states. Nothing in this final rule prohibits SBEs from choosing not to streamline their state training or certification requirements to align with the required training in the FFEs. We believe it is important to provide SBEs with enhanced flexibility and the autonomy to design, provide, and implement the training that is the best fit for their communities.

The streamlined training requirements will still cover how to serve vulnerable and underserved consumers as a required topic, and still require that Exchanges develop and publicly disseminate a set of training standards for Navigators to ensure Navigators are qualified to engage in Navigator activities. Additionally, the required Navigator certification and recertification trainings will not be the only source of training that HHS will provide to best educate Navigators in the FFEs on the complexities of the enrollment process, how to best serve vulnerable and underserved consumers, and how to serve consumers in ways which are culturally and linguistically appropriate. In addition to the required training, HHS will continue to provide training through other channels. These channels include webinars, policy briefs, job aids, newsletters, and fact sheets. HHS is committed to providing Navigators with sufficient training, and will continue to identify and provide trainings in areas in which it may be needed.

Comment: Many commenters expressed concern that because all Navigator entities, as recipients of federal funds, must comply with section 1557 of the PPACA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and the Americans with Disabilities Act, it is essential for HHS to continue to provide training on these topics. These commenters also expressed concern that if training on these topics were no longer required, Navigators would be unable to learn how to comply with these laws. These commenters also expressed their belief that Navigators often serve consumers who have disabilities, chronic illness, or Limited English Proficiency (LEP), and stated that if how to serve these populations were no longer a required training topic, Navigators would be unable to serve these consumers effectively.

Response: We understand that Navigators must comply with anti-discrimination laws and intend to continue to provide information about this topic as part of the broader required training category for serving vulnerable and underserved consumers required training category. We interpret the requirement for training standards to ensure the entities and individuals are qualified to engage in Navigator activities related to the needs of underserved and vulnerable populations to include topics such as:

enrollment assistance personnel. However, at this time, this program is no longer in operation in the FFEs.

- An overview of anti-discrimination laws such as section 1557 of the PPACA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act and the Americans with Disabilities Act;
- Navigators' legal responsibility to comply with the above laws;
- Best practices for how to do so; and
- How to serve underserved and vulnerable consumers, including those who serve consumers who may have disabilities, chronic illness, or a Limited English Proficiency (LEP).

We will monitor implementation of the revised Navigator trainings and their impact to ensure that these underserved and vulnerable populations continue to be properly served by the Navigator program. If HHS sees significant evidence that the capacity of Navigators to serve these populations and comply with anti-discrimination laws has eroded after these changes are implemented, we are open to reconsidering our approach.

Comment: We received comments in support of the flexibility the rule grants to SBEs to choose whether their Navigators should continue to be required to provide certain types of assistance, including post-enrollment assistance, or whether that should be optional.

Response: We agree with the commenters who supported the enhanced flexibility that the rule provides. We also agree that SBEs should have the flexibility to either act in accordance with this rule by making certain types of assistance, including post-enrollment assistance, optional, or to continue to require it. We believe that SBEs, rather than the federal government, are best suited to determine the needs of the populations they serve, and how to best prioritize the work Navigators provide to meet those needs. This final rule provides SBEs with flexibility and autonomy to allocate their resources in ways that best serve the citizens of their states.

Comment: Many commenters also expressed concern about the proposal that makes providing certain types of assistance, including post-enrollment assistance, optional in the FFE. Commenters stated that the vulnerable populations that Navigators serve require ongoing assistance after enrollment and that Navigators play an important role in educating consumers on how to use insurance once they are enrolled, including their role in assisting consumers on how to file an appeal; how to report fluctuating income to the Exchange; how to reconcile their APTC; how to provide referrals to state agencies; how to answer consumers' questions about their health plans; how to provide education to improve consumers' health literacy; how to help consumers locate providers; and how to answer billing and payment questions.

Commenters also stated that because of the trusted relationships Navigators build with consumers during the enrollment process, Navigators are best suited to provide the post-enrollment assistance that those consumers need.

We also received comments that if providing certain types of assistance, including post-enrollment assistance, became optional rather than required, consumer health literacy and health equity may be impacted.

Response: Nothing in this final rule prohibits Navigators in the FFE from providing these types of assistance. If Navigator grantees operate in areas where significant assistance in these areas is needed, those Navigator grantees retain the option to continue providing that assistance, and we would encourage them to continue to do so.

We believe that, just like in the SBEs, Navigator grantees themselves, rather than the federal government, are in the best position to determine the particular needs of the communities they serve, and the type of assistance that is required to meet those needs. We also are committed to improving health equity, and encourage Navigators to continue their important efforts to reduce health disparities in the communities which they serve.

This final rule provides Navigator grantees with flexibility to serve their consumers according to consumer demand, community needs, and organizational resources; and allows Navigators to prioritize their work accordingly.

If Navigator grantees decide to continue to provide the types of assistance that will no longer be required, they and the Exchange are required to ensure that they are appropriately trained to provide that assistance. The FFEs will continue to provide training on post-enrollment assistance via webinars, policy briefs, job aids, newsletters, fact sheets, and other resources, as needed, and urge those Navigators to review those resources and attend those trainings.

Comment: We sought comment on the amount of time Navigators spend providing the types of assistance that will no longer be required, including post-enrollment assistance. Many commenters noted that the time Navigators spent providing such assistance was manageable, and that Navigators did not want or need the flexibility the rule provides. These commenters stated that enrollment assistance needs lessen after the conclusion of the open enrollment period, and therefore, that Navigators had the needed time to provide post-enrollment assistance.

Response: We appreciate those who submitted comments on the amount of time spent providing the types of assistance that will no longer be required, including post-enrollment assistance. We believe the needs of the populations served by Navigators are not static, and not all communities have the same needs. The resources each Navigator may have to devote to providing this assistance may vary by grantee. We believe that it is essential to provide Navigators with as much flexibility and autonomy as possible to prioritize their work according to consumer demand, community needs, and organizational resources.

Comment: Many commenters suggested that rather than making certain types of assistance, including post-enrollment assistance, optional, and streamlining the required Navigator training standards, HHS should instead allocate more funding to the Navigator program.

Response: When Exchanges were in their infancy and public awareness and understanding of coverage options was low, HHS encouraged Navigators to provide intensive face-to-face assistance to consumers. This assistance included providing certain types of assistance, including post-enrollment assistance, as a required duty. It also guided the development of our training standards in past years. Since that time, public awareness and education on options for coverage available through the Exchanges has increased. Certified application counselors, direct enrollment partners, and Exchange-registered agents and brokers serve as additional resources for education on coverage options and outreach to consumers. We believe it is appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the Exchanges.

c. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§ 155.215)

For a discussion of the provisions of this final rule related to standards applicable to Navigators subject to

§ 155.215, please see the preamble to § 155.210.

d. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

Throughout the preamble for §§ 155.220 and 155.221, we proposed to use the term ''web-broker'' to refer to an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection of and enrollment in QHPs offered through the Exchange, a process referred to as direct enrollment. We have used the term ''web-broker'' in the preamble of prior rules, as well as in guidance, and proposed to generally replace the previously used informal definition with the one proposed in this rulemaking.[124] We proposed to define ''web-broker'' in § 155.20 and use that term in §§ 155.220 and 155.221, where applicable, to avoid confusion. We clarified that general references to agents or brokers would also be applicable to web-brokers when a web-broker is a licensed agent or broker. We also proposed to define ''direct enrollment technology providers'' as a type of web-broker that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker under §§ 155.220(c)(3) and 155.221. The proposed definition of web-broker reflected the inclusion of direct enrollment technology providers. Therefore, references to ''web-brokers'' were intended to include direct enrollment technology providers, as well as licensed agents or brokers that develop and host non-Exchange websites to facilitate QHP selection and enrollment, unless indicated otherwise. Please see the preamble discussion related to § 155.221 for further details. As noted above, we are finalizing these definitions as proposed.

As described in the preamble to § 155.221, we proposed significant changes to § 155.221 to streamline and consolidate the requirements applicable to all direct enrollment entities—both issuers and web-brokers—in one regulation. To reflect these changes, we also proposed several amendments to § 155.220. First, we proposed to move certain requirements that apply to all direct enrollment entities from § 155.220 to § 155.221. Specifically, we proposed to move the requirements currently captured in § 155.220(c)(3)(i)(K) and (L), and to amend the requirement currently in (L), which as described further below, are now at § 155.221(b)(4) and (d), respectively. We are finalizing these changes as proposed.

We proposed conforming edits throughout § 155.220 to incorporate the use of the term ''web-broker,'' as proposed to be defined, in applicable paragraphs to more clearly identify which FFE requirements extend to web-brokers. In the introductory text to paragraphs (a), (c), and (d), and in paragraphs (c)(1), (c)(5), (e), (f)(1), (f)(2), (f)(3), (f)(3)(i), (f)(4), (g)(1), (g)(2), (g)(2)(iii), (g)(2)(iv), (g)(4), (g)(5)(i)(A), (g)(5)(i)(B), (g)(5)(ii), (g)(5)(iii),[125] (h)(1), (h)(2), (h)(3), (i), (j)(1), (j)(3), (k)(1), (k)(2), and (l), we proposed to add a reference to web-broker each time agents or brokers are referenced, to clarify that these paragraphs also apply to all web-brokers, including direct enrollment technology providers. In paragraphs (c)(3)(i), (c)(3)(i)(A), (c)(3)(ii), (c)(4), (c)(4)(i), (c)(4)(i)(E), (c)(4)(i)(F), and (c)(4)(ii), we proposed to replace some references to ''agent or broker'' with references to ''web-broker'' to clarify when these paragraphs apply to only web-brokers, and not to other types of agents or brokers who do not host or develop a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the FFEs or SBE–FPs. We also proposed to revise the section heading for § 155.220 to ''Ability of States to permit agents, brokers, and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs'', as well as the section heading for paragraph (i) to similarly add a reference to web-broker. We are finalizing these changes as proposed. Please see the preamble discussion related to § 155.221 for further details on other proposed and finalized changes related to streamlining these regulations and clarifying the requirements applicable to web-brokers and other direct enrollment entities.

We also proposed to amend § 155.220(c)(3)(i) to add a new paragraph (c)(3)(i)(K) that requires web-broker websites to comply with the applicable requirements in § 155.221 when an internet website of a web-broker is used to complete the QHP selection. We noted this new proposed requirement would also apply when an internet website of a web-broker is used to complete the Exchange eligibility application, through the existing cross reference to paragraph (c)(3)(i) in paragraph (c)(3)(ii)(A), but the applicable requirements under § 155.221 may differ depending on whether the non-Exchange website is used to complete the Exchange eligibility application or is used to complete the QHP selection. We are finalizing this amendment as proposed. Please see the preamble discussion related to § 155.221 for further details.

We also proposed to amend § 155.220(c)(3)(i) to add a new requirement at new paragraph (c)(3)(i)(L) that prohibits web-broker websites from displaying recommendations for QHPs based on compensation the web-broker, agent, or broker receives from QHP issuers. In the proposed rule, the term ''compensation'' would include commissions, fees, or other incentives as established in the relevant contract between an issuer and the web-broker. In the proposed rule, we recognized that web-broker websites often ask for certain information from consumers to assist with the display and sorting of QHP options on their non-Exchange websites. This may include estimated annual income, preferences regarding health care providers, prescription drugs the consumer takes, expected frequency of doctors' visits, or other information. We also acknowledged that web-brokers sometimes display QHP recommendations or assign scores to QHPs using the information they collect. We expressed support for the development and use of innovative consumer-assistance tools to help consumers shop for and select QHPs that best fit their needs, consistent with applicable requirements. However, we noted that we believe such recommendations should not be based on compensation web-brokers, agents, or brokers may receive from QHP issuers when consumers enroll in QHPs offered through Exchanges using web-broker non-Exchange websites. We are finalizing this amendment as proposed with the following clarification in response to comments. The definition of the term ''compensation'' for this

[124] HHS previously defined the term ''web-broker'' as including an individual agent or broker, a group of agents and brokers, or a company that is interested in providing a non-Federally-facilitated Exchange website to assist consumers in the QHP selection and enrollment process as described in § 155.220(c)(3).

[125] We also proposed minor technical edits to the last sentence of paragraph (g)(5)(iii) to more closely align this provision with the language at paragraph (g)(4), which establishes similar parameters following the termination of an agent's, broker's, or web-broker's agreements and registration with the FFEs.

purpose includes commissions, fees, or other incentives granted by an issuer to a web-broker, agent, or broker. The inclusion of a reference to agents and brokers in this definition more closely aligns with the intent, which was to prohibit the display of QHP recommendations based on compensation received by any of these three entities from QHP issuers. The remaining revisions to the meaning of ''compensation'' are intended to capture any remuneration or incentives granted by an issuer, whether they be granted pursuant to the terms of a written contract or otherwise.

We also proposed to amend § 155.220(c)(4)(i)(A) to require a web-broker to provide HHS with a list of the agents or brokers who, through a contract or other arrangement, use the web-broker's non-Exchange website to assist consumers with completion of QHP selection or for the Exchange eligibility application, in a form or manner to be specified by HHS. We explained that authority currently exists for HHS to request this information for agents or brokers who, through a contract or other arrangement, use the non-Exchange website to complete the QHP selection process.[126] However, due to the trend of increased use and expansion of direct enrollment pathways for QHP enrollment, we explained that we believe it was appropriate to collect this information proactively and to also extend its collection to include the use of web-broker non-Exchange websites for completion of the Exchange eligibility application, so that we may investigate and respond more efficiently and effectively to any potential instances of noncompliance that may involve agents or brokers using a web-broker's direct enrollment pathway. Having this information would, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We explained that we anticipate issuing further guidance on the form and manner for these submissions and were considering requiring the list must include, at minimum, each agent's or broker's name, state(s) of licensure, and National Producer Number. We further noted that we were considering adopting quarterly or monthly submission requirements, except for the month before the individual market open enrollment period and during the individual market open enrollment period, during which we were considering adopting weekly or daily submission requirements. We noted we were also considering requiring the submission of this data via email using an encrypted file format, such as a password-protected Excel spreadsheet, or alternatively requiring submission through a secure portal. We invited comments on the frequency and manner for these submissions, as well as other data elements that we should consider for inclusion as part of this required reporting. We also proposed to remove the final clause in § 155.220(c)(4) that limits the scope of that section to agents or brokers using web-broker websites who are listed as the agent of record on the enrollments. Several years of experience observing web-broker operations has informed us that web-brokers often submit an entity-level National Producer Number for all QHP enrollments completed through their websites. Therefore the web-broker business entity is the agent of record. However, the requirements stated in § 155.220(c)(4) are intended to apply broadly to agents or brokers using web-broker non-Exchange websites to assist with QHP selections and enrollments. We explained that we believe the existing requirements for web-brokers that provide access to their non-Exchange websites to other agents and brokers, such as verifying agents or brokers are licensed in the states in which they are assisting consumers and have completed the FFE registration process (see § 155.220(c)(4)(i)(B)), as well as reporting to HHS and applicable state departments of insurance any potential material breaches of applicable § 155.220 standards (see § 155.220(c)(4)(i)(E)), should apply broadly to agents and brokers using web-broker non-Exchange websites, and not only to those listed as the agents of record. We are finalizing the changes to § 155.220(c)(4)(i)(A) as proposed. We intend to issue guidance regarding the form and manner for submission of information by web-brokers to HHS regarding the agents or brokers who use the web-broker's non-Exchange website to assist with the completion of QHP selection or the Exchange eligibility application.

Currently, § 155.20 defines an ''agent or broker'' as a person or entity licensed by the state as an agent, broker, or insurance producer. Under § 155.220(d), an agent or broker that enrolls individuals in QHPs in a manner that constitutes enrollment through the Exchange or assists individuals with applying for APTC or cost-sharing reductions must execute an agreement with the Exchange, register with the Exchange, receive training, and comply with the Exchange's privacy and security standards. When these regulatory provisions were originally drafted, it was anticipated that agents and brokers were predominantly individuals. However, with the expansion of direct enrollment, there are more FFE agents and brokers, including web-brokers, that have obtained FFE registration in their capacities as licensed business entities, and not in their individual capacities as licensed agents or brokers (non-individual entities). As noted in the proposed rule, certain regulatory requirements, such as those regarding training are less suited for these non-individual types of licensed agents or brokers. For example, to comply with the requirement to complete training at § 155.220(d)(2), we currently require agents or brokers that are registered with the FFEs as non-individual entities to designate an individual to take training on the entity's behalf, even though all individual agents or brokers assisting FFE consumers through the entity have to complete the training as individual agents and brokers. Because the training is not designed for representatives of a non-individual entity who are not providing direct assistance to FFE consumers, we explained that we believed it is appropriate to remove this requirement for licensed agent or broker non-individual entities. Therefore, we proposed to amend § 155.220(d)(2) to exempt from the training requirement a licensed agent or broker entity that registers with the FFE in its capacity as a business organized under the laws of a state, and not as an individual person. We also explained that we did not intend for this change to alter the requirement that individual agents or brokers must complete training, as applicable, as part of the annual FFE registration process. Therefore, all individual agents and brokers interacting with individual market FFE or SBE–FP consumers, whether working independently or with a non-individual agent or broker entity, including web-brokers, would continue to be required to complete annual training. Individual agents or brokers interacting with FFE–SHOP or SBE–FP–SHOP consumers would continue to be encouraged to take FFE training on an annual basis. We also proposed to include language in § 155.220(d)(2) to clarify that direct enrollment technology providers will not be required to complete FFE annual training because these non-individual entities will not be interacting with individual market FFE or SBE–FP consumers without the assistance of an individual agent or broker; they are

[126] See § 155.220(c)(4)(i)(A).

another example of a non-individual entity for which this training requirement is less suited. We are finalizing these amendments as proposed.

To improve program integrity, we proposed to delete the existing § 155.220(g)(3) and add new paragraphs (g)(3)(i) and (ii) to allow HHS to immediately terminate an agent's or broker's agreement with the FFEs for cause with notice to the agent or broker if an agent or broker fails to comply with the requirement to maintain the appropriate license under state law in every state in which the agent or broker actively assists consumers with selecting or enrolling in QHPs offered through the FFEs or SBE–FPs. We noted that the FFE agreements required under §§ 155.220(d) and 155.260(b) that agents and brokers execute with the FFEs as part of the annual FFE registration process include the requirement to maintain valid licensure in every state that the agent or broker assists Exchange consumers. State licensure as an agent, broker, or insurance producer is a critical consumer protection to ensure that when assisting Exchange consumers these individuals and entities are familiar with rules and regulations applicable in all states in which they provide assistance to FFE or SBE–FP consumers. Licensure in every state where the agent or broker is actively assisting FFE or SBE–FP consumers is a predicate requirement to registering with the FFEs to provide such assistance. We explained that allowing for immediate termination of an agent's or broker's agreements with the FFEs for failure to adhere to the applicable state licensure requirements ensures that an unlicensed individual may not continue to possess the agent/broker role that enables access to the FFEs or SBE–FPs to provide assistance to Exchange consumers as an agent or broker during the advance 30-day notice period that would otherwise apply under the current § 155.220(g)(3). We explained that we believed allowing for immediate termination in these circumstances is appropriate to protect consumers, as well as Exchange operations and systems. Under this proposal, we would confirm information about licensure (or the lack thereof) with the applicable state regulators prior to taking action under the new paragraph (g)(3)(ii). In addition, we proposed that an agent or broker whose agreements with the FFEs are immediately terminated for cause under the new proposed paragraph (g)(3)(ii) would be able to request reconsideration under § 155.220(h). We further proposed amendments to paragraph (g)(4), such that, consistent with other terminations for cause under paragraph (g)(3), immediate terminations under the new proposed paragraph (g)(3)(ii) would result in the agent or broker not being registered with the FFEs or permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in QHPs through the FFEs or SBE–FPs or assist individuals in applying for APTC and cost-sharing reductions (CSRs) for QHPs after the applicable period has elapsed. However, in these circumstances, the agent or broker would be required to continue to protect any personally identifiable information accessed during the term of his or her or its agreements with the FFEs. We also proposed to create a new paragraph (g)(3)(i) to retain the existing language describing the current notification process and timelines for termination for cause under paragraph (g) with advance 30-days' notice, except that we proposed a clarifying edit to reflect that the new paragraph (g)(3)(ii) would constitute an exception to the current process described in existing paragraph (g)(3). As detailed earlier in this preamble, we also proposed to add a reference to web-broker to the existing paragraph (g)(3) (proposed as new paragraph (g)(3)(i)) to clarify this paragraph also applies to web-brokers. We are finalizing these amendments as proposed.

To promote information technology system security in the FFEs and SBE–FPs, including the protection of consumer data, we proposed to amend § 155.220(k) by adding a new paragraph (k)(3) that would continue to allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction. We noted that this proposed language was identical to an existing provision that applies when an internet website of an agent or broker is used to complete QHP selection at current § 155.220(c)(3)(i)(L) [127] and a similar provision applicable to QHP issuers participating in direct enrollment at current § 156.1230(b)(1).[128] In proposed § 155.220(k)(3), we noted our intent for this provision to apply to agents and brokers who, once registered under § 155.220(d)(1), obtain credentials that provide access to FFE systems that may be misused in a manner that threatens the security of the Exchange's operations or information technology systems. We explained that we believe this proposed change was necessary to ensure that HHS can continue to take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers. Because the potential risks posed by agents and brokers with access to FFE systems are similar to those posed by web-brokers or QHP issuers participating in direct enrollment, we explained that we believe this change was necessary and appropriate to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We noted that agents and brokers whose ability to transact information with the Exchange is suspended under this proposed authority would remain registered with the FFEs and authorized to assist consumers using the Marketplace (or side-by-side) pathway,[129] unless and until their agreements are suspended or terminated under § 155.220(f) or (g). We are finalizing this change as proposed.

To further improve program integrity, we proposed in a new § 155.220(m) several additional areas in which we proposed to regulate web-brokers differently from agents or brokers. We explained that we believe these additional proposed changes in new paragraph (m) are important to further protect against potential fraudulent enrollment activities, including the improper payment of APTC and CSRs, to safeguard consumer data and Exchange operations and systems, and to ensure direct enrollment remains a safe and consumer-friendly enrollment pathway.

At § 155.220(m)(1), we proposed to allow a web-broker's agreement(s) to be suspended or terminated for cause under § 155.220(g), or a web-broker to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), based on the actions

[127] This provision also currently applies when an internet website of an agent or broker is used to complete the Exchange eligibility application through the existing cross reference to paragraph (c)(3)(i) in § 155.220(c)(3)(ii)(A).

[128] As described elsewhere in this rule, we are finalizing the proposed deletion of §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) and replacement with similar authority in § 155.221(d) that will be applicable to all direct enrollment entities.

[129] For more information on the Marketplace pathway, please see the Health Insurance Marketplace Guidance: Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplace (November 8, 2016) Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace_Nov-2016_Final.pdf.*

of its officers, employees, contractors, or agents. For example, if the actions of such individuals or entities are in violation of any standard specified in § 155.220, any terms or conditions of the web-broker's agreements with the FFEs, or any applicable federal or state statutory or regulatory requirements, whether or not the officer, employee, contractor, or agent is registered with the FFEs as an agent or broker, the web-broker's agreement(s) may be terminated under paragraph (g)(3) if HHS determines the specific finding of noncompliance or pattern of noncompliance is sufficiently severe. Similarly, if HHS reasonably suspects that an officer, employee, contractor, or agent of a web-broker may have engaged in fraud, whether or not such individual or entity is registered with the FFEs as an agent or broker, HHS may temporarily suspend the web-broker's agreement(s) for up to 90 days consistent with § 155.220(g)(5)(i)(A).

At § 155.220(m)(2), we proposed to allow a web-broker's agreement to be suspended or terminated under § 155.220(g) or to deny it the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g). In general, for purposes of this provision, we proposed to define ''common ownership or control'' based on whether there is significant overlap in the leadership or governance of the entities. We also proposed to collect data during the web-broker onboarding process to assist with the analysis of whether the web-broker is under the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g).

At § 155.220(m)(3), we proposed allowing the Exchange to collect information from a web-broker during its registration with the Exchange, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the FFE as web-brokers. We explained these provisions were important to maintain program integrity, because they will provide authority to collect information that will be used to minimize the risk that an individual or entity can circumvent an Exchange suspension or termination or other enforcement action related to non-compliance. We are finalizing the amendments to create new paragraphs (m)(1), (m)(2), and (m)(3) as proposed.

As noted in the proposed rule, the use of direct enrollment through websites other than HealthCare.gov has expanded, as have the requirements on web-brokers seeking to participate in FFEs and SBE–FPs. For those reasons, we proposed to modify prior policy that prohibited Navigators and certified application counselors (together referred to here as ''assisters'') from using web-broker websites to assist with QHP selection and enrollment. Our proposal would have permitted, but not required, assisters in FFEs and SBE–FPs, to the extent permitted by state law, to use web-broker websites to assist consumers with QHP selection and enrollment, if the website met certain conditions designed to ensure that assisters were able to use it while still meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers. To promote state flexibility and autonomy under this proposal, SBEs other than SBE–FPs would have had discretion to permit their assisters to use web-broker websites, so long as the web-broker websites that assisters were permitted to use in SBEs, at a minimum, adhered to the standards outlined in the proposal. Also, SBEs could instead have chosen to preserve the prohibition on assister use of web-broker websites.

The expansion of direct enrollment and the implementation of enhanced direct enrollment increased interest in allowing assisters to use web-broker websites to assist consumers with selection and enrollment in QHPs offered through Exchanges. As detailed in the proposed rule, some web-brokers supported this idea, because of the unique role assisters serve in many communities. Some assisters also expressed a desire to use web-broker websites to provide an improved consumer experience by leveraging unique consumer assistance tools many web-brokers developed, such as those that provide access to real-time information on the status of submitted applications and enrollments.

In the proposed rule, we explained that the implementation of enhanced direct enrollment by some web-brokers also presents consumers with an additional method of applying for insurance affordability programs, selecting and enrolling in QHPs offered through Exchanges, and receiving post-enrollment support services. We explained that we believe this new option should be available to all FFE and SBE–FP assisters who provide application and enrollment assistance, provided that the information and assistance the assister provides will remain fair, accurate, and impartial. We also expressed hope that allowing FFE and SBE–FP assisters to use web-broker websites to enroll consumers would encourage collaboration between assisters and web-brokers to the benefit of consumers by providing consumers the most appropriate support at each stage of the Exchange application and QHP selection and enrollment processes. To further support the use of web-broker websites by assisters, we also proposed to amend and replace § 155.220(c)(3)(i)(D) with new requirements for web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law. For FFEs and SBE–FPs, we proposed an optional annual certification process for web-brokers that would have been integrated into the existing annual web-broker registration process, or could have occurred during another time of year, during which a web-broker could have been certified by the Exchange by attesting to its compliance with the QHP data display requirements. We also proposed that if a web-broker website did not facilitate enrollment in all QHPs, it would be required to identify to consumers the QHPs, if any, for which the web-broker website did not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, in a form and manner specified by the Exchange, stating that the consumer could enroll in such QHPs through the Exchange website, and display a link to the Exchange website. However, after consideration of comments, we are not finalizing the proposed modification to the prior policy that prohibited assisters from using web-broker websites or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D). The current policy, which prohibits the use of web-broker websites by assisters, remains in effect. We are also retaining the existing requirement at § 155.220(c)(3)(i)(D), which requires the display of all QHP data provided by the Exchange on non-Exchange websites used to complete QHP selection and/or the Exchange eligibility application.

The following is a summary of the comments received on the proposed amendments, policies and clarifications related to § 155.220. Comments related to the accompanying proposals under § 155.221 are discussed later in this rule.

Comment: Commenters that referred to the proposal at § 155.220(c)(3)(i)(L) to prohibit web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers unanimously supported it. Some commenters also supported prohibiting implicit recommendations based on compensation received from issuers by requiring web-broker websites to display all QHP information provided by the Exchange for all QHPs offered through the Exchange instead of displaying limited details and a standardized disclaimer as permitted under § 155.220(c)(3)(i)(A). One commenter recommended requiring web-broker websites to display the rationale for any QHP recommendations they make.

Response: We are finalizing the amendment as proposed at § 155.220(c)(3)(i)(L). As stated above, we are amending the definition of the term ''compensation'' for this purpose to include commissions, fees, or other incentives provided by a QHP issuer to the agent, broker, or web-broker. This better aligns with our intent, as well as comments received in support of the proposal, to prohibit the display of QHP recommendations on web-broker websites based on compensation an agent, broker, or web-broker receives from QHP issuers. While we acknowledge that web-broker websites may implicitly recommend QHPs based on compensation they receive from QHP issuers, we did not propose and are not establishing standards in this final rule in this regard. However, we intend to monitor implementation and effectiveness of the new standard finalized at § 155.220(c)(3)(i)(L), which prohibits the display of QHP recommendations on web-broker websites based on compensation received from QHP issuers, and may consider proposing additional standards related to the display of QHP recommendations on web-broker websites, including requiring the display of a rationale for any QHP recommendations, in future rulemaking.

We also clarify that under § 155.220(c)(3)(i)(A), a web-broker website used to complete QHP selection or the Exchange eligibility application must disclose and display all QHP [130] information provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c). If not directly provided by the Exchange, a web-broker may obtain additional information on QHPs displayed on its website directly from those QHP issuers with whom it has a contractual relationship. In accordance with § 155.220(c)(3)(i)(A), if a web-broker does not have access to all of the comparative information required under § 155.205(b)(1) and (c) for a QHP offered through the Exchange, such as premium or benefit information, it must display the required standardized Plan Detail Disclaimer for the specific QHP.[131]

Comment: Several commenters supported the proposal at § 155.220(c)(4)(i)(A) to require web-brokers to provide HHS with a list of agents and brokers who enter into a contract or other arrangement to use the web-broker's website to assist consumers with Exchange applications and QHP selections. One commenter recommended the list be required annually and limited to include agents and brokers who have a signed agreement and actually used a web-broker's website to assist with QHP enrollment in the past year, and not any agents or brokers that could potentially have used the web-broker's website for that purpose but did not, in the interest of reducing burden. Another commenter expressed concern about the scope of this proposal and whether it extends beyond agents and brokers using a web-broker's website to business development partners through which it receives referrals.

Response: We are finalizing the amendment as proposed at § 155.220(c)(4)(i)(A). As indicated above, we intend to issue guidance on the form and manner for these submissions and appreciate the desire to minimize the burden of this requirement. That is one of the reasons we are considering adopting a measured, targeted approach to reporting that would reduce the frequency of the submissions for most of the year by adopting quarterly or monthly submission requirements. We continue to believe that more frequent reporting, such as daily or weekly submissions, are more appropriate for the time period spanning from the month before through the entire individual market open enrollment period because of the increased volume of enrollments and the accompanying increased access to FFE systems and consumer information during this time. For this requirement to enable us to more efficiently and effectively investigate and respond to instances of noncompliance, including those situations that may pose risks to Exchange data and systems, we must have the information more frequently than annually. For example, agents, broker, and web-brokers may enter into new relationships and/or end existing agreements at any time during the year. The adoption of an annual reporting schedule would not capture these changes until the following year. As such, there is a risk that the data would become obsolete quickly, hindering our oversight and enforcement efforts. For these reasons, we decline to adopt an annual reporting schedule.

We also believe the data collected must include information about all agents and brokers that are able to use a web-broker's website for direct enrollment, whether or not they have done so recently, since agents and brokers with this access are equally able to access the systems and engage in misconduct that we may need to investigate. In terms of the scope of information that will have to be reported, we clarify it extends only to those agents and brokers that have a current contractual or other arrangement with a web-broker to use its website to assist consumers with the completion of an Exchange eligibility application or QHP selection in the FFE or SBE–FP. Persons or entities only referring consumers to the web-broker's website would not be subject to this requirement.

Comment: Several commenters supported the proposal at § 155.220(g)(3)(ii) to allow for the immediate termination of agreements with agents or brokers for cause if an agent or broker fails to maintain the appropriate state license in every state in which the agent or broker is actively assisting consumers with Exchange applications and QHP enrollment. One commenter pointed out that some national licensure databases contain inaccuracies and it is important to ensure accurate information is used as the basis for termination. Another commenter emphasized the importance of timely and accurate communication between HHS and state regulators as it relates to this proposal.

Response: We are finalizing the amendments to § 155.220(g)(3) as proposed. We appreciate the comments

[130] With some limited exceptions, stand-alone dental plans (SADPs) are considered a type of QHP. See Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule (77 FR 18310, 18315) (March 27, 2012). The same display requirements extend to SADPs, including display of all applicable SADPs offered through the Exchange and all available information specific to each SADP on their websites, as well as including the Plan Detail Disclaimer to the extent that all required SADP comparative information is not displayed on the web-broker's website.

[131] *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-Web-brokers-Displaying-Disclaimers.pdf.*

expressing concerns about the potential for inaccurate data and the need for timely communications with state regulators. We will develop procedures to verify state licensure with applicable state regulators, which may include confirming national database information with information made publicly available by individual states, as well as outreach to state regulators. We also will continue our general efforts to coordinate oversight activities related to agents and brokers with states. In addition, as detailed above, agents or brokers whose agreements with the FFEs are immediately terminated under the new paragraph (g)(3)(ii) will be able to request reconsideration under § 155.220(h).

Comment: We received several comments on the proposals at § 155.220(m) related to the enforcement actions that may be taken against web-brokers. One commenter supported the proposals. One commenter requested we clarify the use of ''agent'' in proposed § 155.220(m)(1), relating to the suspension or termination of a web-broker's agreement with the Exchange under paragraph (g), and the denial of the right for the web-broker to enter into agreements with the FFE under paragraph (k)(1)(i) based on the actions of its officers, employees, contractors or agents (regardless of whether these individuals are registered with the Exchange as an agent or broker). Another commenter expressed concern that these proposals appeared to provide authority to suspend or terminate a web-broker's agreement based on the actions of as few as one agent using the web-broker's website. A fourth commenter stated that the proposals should apply to non-web-broker agent or broker business entities and not only web-broker business entities, and that HHS should provide examples of the actions that could be grounds for termination or suspension of a web-broker's agreements, including whether such actions would need to be related to the operation of the web-broker's website.

Response: We are finalizing these amendments as proposed.

As explained in the proposed rule, the intent of these changes is to provide additional tools for HHS to guard against fraudulent activities, protect consumer data and Exchange operations and systems, and address serious cases of misconduct. Web-broker business entities participating or seeking to participate in direct enrollment are proliferating. In addition, the complexity of web-brokers' technical integrations with Exchange systems are increasing, providing greater access to sensitive consumer data and growing dependencies between Exchange and web-broker systems. After several years of experience observing web-broker operations and participation in the FFEs and SBE–FPs, we found it was necessary to update our oversight and enforcement authority to add tools to combat fraud to align with these changes.

We do not expect this authority will be used against the vast majority of web-brokers that make a good-faith effort to comply with applicable requirements. Further, we anticipate these provisions will have limited impact as they are designed to provide HHS greater flexibility to address the limited instances where there is evidence of significant misconduct or non-compliance by a web-broker, its officers, employees, contractors, or agents. We clarify that ''agent'' as referred to in § 155.220(m)(1) is intended to refer to an individual or entity with a business relationship with a web-broker such that the entity or individual is authorized to act on behalf of the web-broker. ''Agent'' in this context may or may not refer to a licensed agent or broker registered with the FFEs to assist Exchange consumers, unless the licensed agent or broker is also authorized to act on behalf of the web-broker. We believe this new authority will close some current gaps in oversight of web-brokers, such as those that exist when an individual or entity registered with the FFEs is denied the right to enter into FFE agreements for future benefit years under § 155.220(k)(1)(i) due to misconduct and the individual or entity tries to avoid the implications of the enforcement action by creating a new web-broker business entity that seeks to register with the FFEs before the expiration of the penalty under § 155.220(k)(1)(i). Examples of the types of activities that could give rise to enforcement action under these new authorities are a web-broker's officer instructing his agent/broker employees to falsify data submitted on consumers' Exchange applications, a documented pattern by a web-broker entity of misusing Exchange consumer data, or the failure to adopt procedures to properly secure data and comply with applicable privacy and security requirements. As these examples illustrate, the activities for which an enforcement action may be taken under this authority are not limited to activities related only to the operation of a web-broker's website.

While each enforcement action is fact-specific, we generally clarify that if a registered agent or broker is believed to have engaged in noncompliance that we discover through our oversight of web-broker websites, and there is no evidence that the web-broker was part of the noncompliance activities, we would take the enforcement action against the agent or broker (and not the web-broker). However, if the investigation reveals facts that indicate the web-broker was involved in the non-compliance, then we may also take action under this new authority against the web-broker (in addition to taking appropriate action for the agent or broker involved). We may consider expanding this authority to non-web-broker agent or broker business entities in the future. However, the specific concerns and potential risks the proposals were intended to mitigate are posed most acutely by web-brokers by virtue of the more direct and expansive access they have to Exchange systems and consumer data. Therefore, we proposed and are finalizing this authority as limited to web-brokers at this time.

Comment: Numerous commenters opposed the proposal to allow assisters to use web-broker websites and the proposed new regulations that would have replaced the existing § 155.220(c)(3)(i)(D). Commenters were concerned about whether assisters could remain fair and impartial if they were assisting consumers using web-broker websites that did not offer enrollment into all QHPs offered through the Exchange, or that included QHP recommendations. Some commenters highlighted the confusion assisters and consumers may encounter when using web-broker websites that include marketing for non-QHP products. One commenter opposed any proposed expansion to the role of assisters.

Some commenters supported prohibiting web-broker websites from recommending QHPs if this proposal was finalized. One commenter suggested that assisters should only be permitted to use web-broker websites that exclusively market QHPs, and web-brokers should not receive commissions for consumers enrolled in QHPs through a web-broker website if the consumers received support from assisters. Another commenter advocated for mandatory certification of web-broker websites before assisters may use them. One commenter supported requiring web-broker websites to develop a separate pathway exclusively for assisters to use. One commenter recommended allowing web-brokers to compensate assisters to supplement federal funding for assisters, and noted that the compensation should be unrelated to whether the web-broker received a commission associated with the assistance provided to the consumer by the assister, and should include

compensation for assistance provided to consumers who are determined eligible for Medicaid.

Some commenters supported specific elements of the proposal. Several commenters supported the flexibility proposed to be provided to SBEs, other than SBE–FPs, to either permit their assisters to use web-broker websites or to instead preserve the prohibition on assister use of these non-Exchange websites. One commenter supported the proposed requirement that web-broker websites display all QHP data provided by the Exchange before assisters could use the websites. One commenter that generally supported the proposal described a potential outcome of the proposal would be the development of new consumer-assistance tools that assisters would be able to leverage when using a web-broker website to assist consumers.

Response: We agree with commenters that there are concerns related to assister use of web-broker websites that warrant further consideration, and therefore, we are not finalizing the proposed modification to the prior policy that prohibits assisters from using web-broker websites or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D) at this time. Adoption of approved enhanced direct enrollment functionality by web-brokers remains limited and we have decided to focus on the implementation and oversight of the enhanced direct enrollment pathway before allowing the use of web-broker websites by assisters. This approach also allows web-brokers interested in participating in enhanced direct enrollment to focus on implementing and complying with those new requirements at this time. In addition, new insights may be gained about how best to approach and implement this policy change as more web-brokers are approved to participate in enhanced direct enrollment and we gain more experience with enhanced direct enrollment pathways generally. We intend to monitor these changes and may revisit the current policy regarding assister use of these websites including comments received on the policies in the proposed rule, at a later date. We believe assisters remain a critical component of the options available for consumers to receive support completing the Exchange eligibility application and selecting and enrolling in QHPs, especially for certain vulnerable populations that have historically unmet needs. The current policy, which prohibits the use of web-broker websites by assisters, remains in effect and we are also retaining the existing requirement at § 155.220(c)(3)(i)(D).

e. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

Direct enrollment is a mechanism for third parties to directly enroll consumers seeking QHPs through a non-Exchange website in a manner considered to be through the Exchange. Direct enrollment was created to provide consumers different options to shop for and enroll in QHPs offered through the Exchange. The entities that have been authorized to offer direct enrollment pathways to date are QHP issuers, as well as agents and brokers that develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs, referred to as web-brokers. As described above, in this rule we finalized a new definition for the term ''web-broker.'' Consistent with this new definition, we use the term web-broker throughout this final rule when we are referring to agents and brokers that develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs offered through an Exchange, otherwise known as direct enrollment, as well as direct enrollment technology providers. The original version of direct enrollment, or classic direct enrollment, is still in operation. It utilizes a double redirect from a direct enrollment entity's website where QHP shopping occurs, to HealthCare.gov where the eligibility application is completed, and back to the entity's website to finalize the selection of the QHP. Classic direct enrollment allows QHP issuers and web-brokers who meet applicable requirements to design and host a plan shopping experience, and assist consumers with the QHP selection process using relatively simple and limited application programming interfaces (APIs). The FFE direct enrollment program has expanded beyond the classic (that is, double-redirect) direct enrollment pathway as the FFEs' technical capabilities have significantly increased, beginning with proxy direct enrollment for plan year 2018 [132] and continuing with the implementation of enhanced direct enrollment for plan year 2019 and beyond.[133] The requirements and technical expertise needed to participate in each new iteration of direct enrollment have similarly increased as participants have greater access to and responsibility for sensitive consumer data and Exchange systems. With enhanced direct enrollment, HHS allows participants to create and host a dynamic eligibility application and integrate several new APIs that facilitate eligibility determinations, as well as the consumer's enrollment in a QHP, and data sharing with the applicable Exchange. Enhanced direct enrollment provides new options for consumers to receive more comprehensive services through a non-Exchange website, without the need to redirect to HealthCare.gov, for application and enrollment and ongoing support throughout the plan year. We explained in the proposed rule that we believe this will promote innovation and competition, and ultimately lead to better experiences for more consumers. We also noted that streamlining and consolidating regulatory requirements, when possible, will simplify the otherwise complex requirements to participate in direct enrollment and make it easier for direct enrollment entities and organizations interested in participating in direct enrollment to understand and comply with applicable requirements. We also explained that the complex and evolving nature of direct enrollment requires updates to accommodate innovation, ensure program integrity, and protect sensitive consumer data.

As detailed in the proposed rule, the entities that have been permitted to offer direct enrollment pathways to date have been QHP issuers and web-brokers that develop and host non-Exchange websites to facilitate selection of and enrollment in QHPs offered through an FFE or SBE–FP. Direct enrollment regulatory provisions have likewise been divided into sections separately applicable to QHP issuers participating in direct enrollment and web-brokers. As direct enrollment has evolved with the implementation of enhanced direct enrollment, many of the requirements applicable to QHP issuers performing direct enrollment and web-brokers have become increasingly similar. Therefore, we proposed to revise § 155.221 to apply to all types of direct enrollment entities and to expand the requirements captured in this regulation beyond audits of direct enrollment entities. To reflect this change we also proposed to revise the section heading of § 155.221 to ''Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.''

[132] Proxy direct enrollment was implemented on a temporary basis for plan year 2018. More information is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-for-the-Proxy-Direct-Enrollment-Pathway-for-2018-Individual-Market-Open-Enrollment-Period.pdf.*

[133] 81 FR at 94118.

As detailed above, we also proposed to amend § 155.20 to include definitions of several terms we proposed to use in § 155.221 including: ''direct enrollment entity'' and ''web-broker.'' Specifically, we proposed to define ''direct enrollment entity'' as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We proposed to define ''web-broker'' as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. As explained elsewhere in this preamble, we also proposed to define the term ''web-broker'' to include direct enrollment technology providers. We explained that it is important to distinguish ''web-brokers'' from other agents and brokers utilizing a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the Exchanges when they did not develop and do not host the non-Exchange website. Stated differently, agents and brokers using a non-Exchange website developed and hosted by a web-broker are not themselves necessarily web-brokers. For the reasons outlined in the preamble to § 155.220, we are of the view that it is appropriate to impose different requirements on web-brokers and agents and brokers who are not web-brokers. The proposed definition and the proposed changes to §§ 155.220 and 155.221 reflect this approach and would enable web-brokers, agents, and brokers to more clearly identify when requirements are applicable to only web-brokers.

We also proposed to amend § 155.20 to define ''direct enrollment technology provider'' as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. This definition captures instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent, broker, or producer to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, but otherwise is functioning as a web-broker, we proposed that these technology companies would be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.[134] The proposed definition of ''web-broker'' reflects the inclusion of direct enrollment technology providers. As detailed above, we are finalizing these definitions as proposed. Please refer to the preamble for § 155.20 for a summary of comments on the proposed definitions.

We proposed to generally maintain the current requirements in § 155.221 that describe the standards for third-parties to perform audits of direct enrollment entities. However, to accommodate new content we proposed to add to this regulation, we proposed to redesignate the existing paragraphs (a) through (c) as paragraphs (e) through (g), respectively.

We also proposed some amendments to existing requirements currently captured in paragraphs (a) through (c), as described more fully below. In addition, throughout the redesignated paragraphs (e), (f), (f)(2), (f)(3), (f)(4), (f)(6), (f)(7), and (g), we proposed conforming edits to change references to agents, brokers, and issuers to direct enrollment entities. We also proposed to update the regulatory cross-references in the redesignated paragraph (f)(6) and (f)(7) from § 155.221(a) to § 155.221(e) to align with other proposed streamlining changes to this regulation. We also proposed to add paragraph headings throughout this revised regulation for further clarity. In paragraph (e), we also proposed to add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with new § 155.221(b)(4) [135] be independent of the entities they are auditing. We proposed this change because we believe an independent audit is less likely to be influenced by a direct enrollment entity's business considerations and therefore is more reliable. We note that current § 155.221(b)(4) requires third-party auditors to disclose to HHS any financial relationships they have with the entities they are auditing. We explained in the proposed rule that we believe this disclosure requirement remains relevant even with the proposed addition to proposed paragraph (e) that will require auditors to be independent, because an auditor may be independent while also contracting with the entity it is auditing (and therefore having a financial relationship with the entity) to perform audits or other activities unrelated to those described in § 155.221. We therefore proposed to retain this disclosure requirement at new § 155.221(f)(4).

We also proposed to clarify in paragraph (e) that an initial audit is required, in addition to subsequent annual audits, and that these audits must include review of the entity's compliance with applicable direct enrollment requirements. These clarifications do not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections,[136] and these audits must confirm compliance with applicable requirements.[137] In paragraph (e), we proposed to add language to clarify that operational readiness must be demonstrated prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or make a QHP selection. This language is consistent with the operational readiness review requirements currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers, which we proposed be moved to § 155.221(b)(4), and accounts for the fact that direct enrollment entities participating in enhanced direct enrollment will host the eligibility application in addition to QHP selection.

We proposed to maintain the last sentence that currently appears in § 155.221(a) as the last sentence of the new paragraph (e) that states the third-party entity will be the downstream or delegated entity of the agent, broker, or issuer that participates or wishes to participate in direct enrollment, replacing the references to agent, broker,

[134] For example, amendments to § 155.220(d)(2) exempt direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

[135] Direct enrollment operational readiness review requirements are currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers.

[136] See § 156.1230(b)(2) for issuers participating in direct enrollment and § 155.220(c)(3)(i)(K) for web-brokers.

[137] See § 155.221(b)(5). Also see § 156.1230(b)(2).

and issuer with direct enrollment entity. In paragraph (f), we proposed to generally maintain the current requirement captured in § 155.221(b) that a direct enrollment entity must satisfy the requirement to demonstrate operational readiness by engaging a third-party entity that complies with the specified requirements.

We also proposed to require under new paragraph (f) that a written agreement must be executed between the direct enrollment entity and its auditor stating that the auditor will comply with the standards outlined in paragraph (f). We proposed this new requirement because we believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement between the parties. We proposed to delete the provision in current paragraph (c) that refers to each third-party entity having to satisfy the standards outlined in current paragraph (b), to avoid duplication with a nearly identical provision in proposed paragraph (f).

We proposed to maintain, in the redesignated new paragraph (g), the provision that clarifies that direct enrollment entities may engage multiple third-party entities to conduct the operational readiness audits under proposed § 155.221(e).

We proposed a new paragraph (a) in § 155.221 that will establish the types of entities the FFEs will permit to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner that is considered to be through the Exchange, to the extent permitted by state law. We proposed to capture in § 155.221(a) the two types of entities that are already permitted by the FFEs to use and offer a non-Exchange website to facilitate direct enrollment: QHP issuers that meet the requirements in § 156.1230 and web-brokers that meet the requirements in § 155.220. New proposed paragraph (a) also reflected that these entities would be required to comply with the applicable requirements outlined in the new proposed § 155.221, which we proposed to capture the direct enrollment requirements that would apply to both web-brokers and QHP issuers participating in direct enrollment. For the remaining requirements that only apply to web-brokers or only apply to QHP issuers participating in direct enrollment, we proposed to retain those requirements in §§ 155.220 and 156.1230, respectively.

In the proposed rule, we described guidance that details several existing display standards applicable to issuers or web-brokers participating in direct enrollment.[138]

We explained that we received feedback from issuers and web-brokers suggesting there was some confusion about the current standards and guidance related to the display of QHPs and non-QHPs on non-Exchange websites used to facilitate direct enrollment. In an effort to clarify expectations, achieve greater uniformity in standards for all direct enrollment entities, and provide flexibility for innovation, we proposed to establish requirements under § 155.221(b) for the FFEs, which would apply to all FFE direct enrollment entities. As noted elsewhere in preamble, some of the proposed requirements in § 155.221(b) were intended to streamline existing web-broker and QHP issuer direct enrollment requirements that are currently separately imposed under §§ 155.220 and 156.1230 by capturing these similar requirements in one regulation. Other proposed standards in § 155.221(b) are new regulatory requirements and are proposed to clarify or otherwise address compliance questions that have arisen under the existing regulations and guidance.

At new § 155.221(b)(1), we proposed to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites. We explained that this proposal was intended to balance the goals of minimizing consumer confusion about distinct products with substantially different characteristics, and allowing marketing flexibility and opportunities for innovation. At § 155.221(b)(2), we proposed to require direct enrollment entities to prominently display a standardized disclaimer in the form and manner provided by HHS.[139] Consistent with current practice for the other standardized disclaimers provided by HHS under §§ 155.220 and 156.1230, we explained we would provide further details on the text and other display details for the standardized disclaimer in guidance, but noted its purpose would be to assist consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs, and for which products APTC and CSRs are available, during a single shopping experience. In new § 155.221(b)(3), HHS proposed that direct enrollment entities must limit the marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that will minimize the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. For example, under the proposed display standards captured at § 155.221(b)(1) through (b)(3), direct enrollment entities would be required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information for non-QHPs and sponsored links promoting health insurance-related products. However, it would be permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complied with the proposed standardized disclaimer requirements. The proposed requirements captured at § 155.221(b)(1)–(3) are intended to provide flexibility for direct enrollment entities to market valuable additional coverage that complements QHP coverage, while also allowing HHS to establish important parameters around the manner and type of non-QHPs that direct enrollment entities may market as part of a single shopping experience with QHPs. We explained that we believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges. But we also appreciate that having flexibility to update these standards would allow us to adapt the display guidance as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also noted our belief that the convenience of being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper safeguards can be put in place. In § 155.221(b)(4), we

[138] See, for example, section 4.3 of the Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollment-Manual-062618.pdf.* Also see, section II.B of the Guidance for Web-brokers Registered with the Federally-Facilitated Marketplaces (October 17, 2016), available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-Web-brokers-FFMs.pdf.*

[139] As proposed, this new standardized disclaimer would be in addition to the existing requirements at § 155.220(c)(3)(i)(A) and (G) for web-brokers and at § 156.1230(a)(1)(iv) for QHP issuers participating in direct enrollment.

proposed to move and consolidate the parallel requirements currently captured in §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) that web-brokers and QHP issuers, respectively, demonstrate operational readiness and compliance with applicable requirements prior to their internet websites being used to complete a QHP selection. We also included language in proposed § 155.221(b)(4) to clarify that operational readiness and compliance with applicable requirements must also be demonstrated prior to their internet websites being used to complete an Exchange eligibility application. We explained that this clarification was important as enhanced direct enrollment is implemented and approved direct enrollment entities are hosting the Exchange eligibility application on their non- Exchange websites. We proposed accompanying amendments to remove the operational readiness requirements from §§ 155.220 and 156.1230 as part of our efforts to streamline the regulatory requirements applicable to direct enrollment entities. Lastly, in § 155.221(b)(5), we proposed to capture the requirement for direct enrollment entities to comply with all applicable federal and state requirements. This would include the additional Exchange requirements in §§ 155.220 and 156.1230 that apply to web-brokers and QHP issuers that participate in direct enrollment, respectively.

In § 155.221(c), we proposed FFE requirements related to direct enrollment entity application assisters. Please see the preamble to § 155.415 for further details.

In § 155.221(d), we proposed to consolidate and amend the existing parallel provisions in §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) to authorize HHS to immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations or Exchange information technology systems until such circumstances are resolved, remedied or sufficiently mitigated to HHS' satisfaction. We proposed to remove the provisions from §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) as part of our efforts to streamline and consolidate the requirements applicable to direct enrollment entities in one regulation. The proposal captured in § 155.221(d) includes language that will extend the authority to suspend the ability to transact information with the Exchange to also include discovery of circumstances by HHS that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations. This addition was necessary and appropriate as enhanced direct enrollment allows direct enrollment entities to collect and transmit the application data that the Exchanges use to complete eligibility determinations.

Lastly, to account for direct enrollment entities that may be assisting consumers in SBE–FP states, we proposed a new § 155.221(h) to clarify that such entities are also required to comply with applicable standards in § 155.221.

We sought comment on all of these proposals. After consideration of the comments received, we are finalizing all of the amendments to § 155.221, as proposed.

Comment: We received numerous comments on the proposals at §§ 155.221(b)(1) and (3) to respectively require that QHPs and non-QHPs be displayed and marketed on separate website pages of non-Exchange websites and to limit marketing of non-QHPs during the Exchange application and QHP selection process. Many commenters supported the proposal to require QHPs and non-QHPs be displayed and marketed on separate website pages on non-Exchange websites. Some commenters were opposed to any marketing of non-QHPs, even after the Exchange application and QHP selection process, on non-Exchange websites. One commenter stated that allowing this type of marketing creates incentives for brokers to advise consumers to spend more money on supplemental plans and less on QHPs, which the commenter was concerned would not be in the consumer's interest. Some commenters specifically cited concerns about the marketing of short-term, limited-duration insurance plans. Some commenters recommended we adopt requirements that help consumers understand the differences between QHPs and non-QHPs, and the availability of financial assistance only applying to QHPs. One commenter agreed with the goal of the proposal to minimize consumer confusion, but was opposed to limiting the marketing of non-QHP products until after the Exchange application and QHP selection processes are complete, and claimed this limitation would suppress web-broker participation. One commenter was opposed to most limits on marketing non-QHPs, and wanted web-brokers to be able to display and market non-QHP alternatives to QHPs, rather than just complementary non-QHP products during the consumer's shopping experience.

Response: We are finalizing the amendments to create new § 155.221(b)(1) and (3) as proposed. As explained in the proposed rule, we have consistently received feedback from QHP issuers and web-brokers about confusion with respect to the current guidance and standards related to the display and marketing of QHPs and non-QHPs on their respective non-Exchange websites. We believe this approach provides additional clarity and represents a balance that minimizes the chance that consumers will be confused about the products being offered to them, including which products APTC and CSRs are available for, while also allowing some marketing of complementary non-QHP products after the Exchange application and QHP selection is complete but during a single shopping experience on non-Exchange websites. This provision will not limit web-brokers or issuers from marketing non-QHP products to consumers outside the Exchange application and QHP selection processes, but if a consumer has decided to complete the Exchange eligibility application or to shop for QHPs on a non-Exchange website, we believe the marketing of non-QHP products to them during that time would cause confusion about which products are offered through the Exchange (and therefore subject to applicable requirements and eligible for APTC and CSRs) and which are not. The disclaimer requirement established at § 155.221(b)(2) is intended to help consumers understand the difference between QHPs and non-QHPs, and that financial assistance is only available for QHPs. We do not believe this policy creates new incentives for brokers to market non-QHP products instead of QHPs. To the extent those incentives exist, they exist with or without this policy. Similarly, we do not believe this policy has any implications specific to the marketing of short-term, limited-duration insurance plans generally. Under § 155.221(b)(1) it is not permissible to display or market any non-QHP plans, including short-term, limited-duration insurance plans, on the same website pages as QHPs.

As described in the proposed rule and above, the requirements at § 155.221(b)(1) through (3) are intended to provide flexibility for direct enrollment entities to market valuable additional coverage that complements QHP coverage, while also allowing HHS to establish important parameters around the manner and type of non-QHPs that direct enrollment entities may market as part of a single shopping

experience with QHPs offered through the Exchange. We may release additional guidance, as may be necessary or appropriate, to further clarify the new standards we are finalizing at § 155.221(b)(1) through (3) for direct enrollment entities that wish to display and market non-QHPs on separate web pages but as part of a single shopping experience with QHPs offered through the Exchange.

f. Certified Application Counselors (§ 155.225)

We proposed allowing, but not requiring, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. We are not finalizing this proposal. For a discussion of the provisions of this final rule related to that proposal, please see the preamble to § 155.220.

3. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Allowing Issuer Application Assisters To Assist With Eligibility Applications (§ 155.415)

In the first Program Integrity Rule,[140] we finalized § 155.415, which allows an Exchange, to the extent permitted by state law, to permit issuer application assisters to assist consumers in the individual market with an Exchange eligibility application if they met certain requirements. At § 155.20, we define issuer application assister as an employee, contractor, or agent of a QHP issuer who is not licensed as an agent, broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. At current § 156.1230(a)(2), when permitted by an Exchange under § 155.415, and to the extent permitted by state law, QHP issuers that elect to use application assisters are required to ensure that each of their application assisters at least: (1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules; (2) complies with the Exchange privacy and security standards consistent with § 155.260; and (3) complies with applicable state law related to the sale, solicitation, and negotiation of health insurance products, including laws related to agent, broker, and producer licensure, confidentiality, and conflicts of interest.

In adopting this approach, we recognized that, in some states, a license may be required to assist an applicant applying for an eligibility determination or redetermination. We deferred to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees as authorized under § 156.1230(a)(2), and whether licensure would be required to provide such assistance. We stated that if state law requires a license to enroll applicants in coverage, then issuers and their application assisters would need to follow state law for licensure requirements. We also recognized that there were certain functions that issuers generally had their staff perform prior to the issuance of the first Program Integrity Rule, such as answering general information about plans, and we wanted to allow those individuals to continue to perform those functions, without meeting additional standards, if permitted by state law. We indicated that, if an issuer wants those individuals to perform additional functions, such as helping consumers as they apply for an eligibility determination or redetermination for coverage through the Exchange, or as they apply for insurance affordability programs, or as they report changes to an Exchange, those individuals could assist consumers with applications subject to the standards in § 156.1230(a)(2), so long as providing such assistance did not otherwise conflict with state law. Additionally, we stated that facilitating selection of a QHP may be a typical function of issuer staff and issuer staff will be able to perform post-eligibility functions such as plan compare and selection, if permitted by state law, without being subject to the standards of § 156.1230(a)(2). As currently codified, the application assister definition and accompanying requirements only apply to issuer application assisters.

As described in the proposed rule, we believe providing parity for direct enrollment entities, when possible, promotes fair competition and maximizes consumer choice. In addition, there was no apparent reason why issuer staff are more qualified to assist consumers with the Exchange eligibility application than the staff of other direct enrollment entities, assuming all receive appropriate training and when otherwise permitted under applicable state law. Therefore, we proposed to expand the flexibility to employ or contract with application assisters to all direct enrollment entities, to create parity between issuers and other types of direct enrollment entities. Accordingly, we proposed changes to several regulatory sections. Specifically, we proposed to amend § 155.20 by adding the term ''direct enrollment entity application assister,'' which we proposed to define as an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. We proposed to adopt the same approach for direct enrollment entity application assisters as the existing one for issuer application assisters. In other words, under our proposal, these application assisters would need to comply with applicable state law, including any licensure requirements, and we would continue to defer to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees and whether licensure is required to provide such assistance.

We also proposed to revise § 155.415(a) to authorize an Exchange, to the extent permitted by state law, to permit issuer and direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs. Additionally, we proposed to maintain language in § 155.415(a) to mandate that all direct enrollment entities who seek to use application assisters, and not just QHP issuers, must ensure that their application assisters meet the standards currently captured in § 156.1230(a)(2), which we proposed to move to new paragraphs (b)(1) through (3) of § 155.415, with two proposed amendments. Currently, § 156.1230(a)(2)(i) requires all QHP issuer application assisters to receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. In the proposed rule, we noted that licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs and SBE–FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assisters to have similar access to FFE systems, so that they are also able to assist consumers as described in this

[140] Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54070 (August 30, 2013).

rule, they will need credentials similar to those obtained by agents and brokers during the FFE registration and training processes. Therefore, we proposed to require that application assisters providing assistance in the FFEs and SBE–FPs complete a similar annual registration and training process as to what is required for agents and brokers under § 155.220(d)(1) and (2), in a form and manner to be specified by HHS, so that they will have the necessary training before being provided credentials to assist consumers and access FFE systems. This proposed new training and registration requirement for application assisters is captured in the new proposed § 155.415(b)(1). Currently, § 156.1230(a)(2)(iii) requires all QHP issuer application assisters to comply with applicable agent, broker, and producer licensure laws, which may not be applicable in a given circumstance. For example, another state licensure law may exist for professionals whose functions are more similar to application assisters than licensed agents, brokers, and producers. We, therefore, proposed to amend this standard (proposed to be redesignated at § 155.415(b)(3)) to require all application assisters to comply with applicable state law related to the sale, solicitation and negotiation of health insurance products, including any state licensure laws applicable to the functions to be performed by the application assister; confidentiality; and conflicts of interest. We did not propose any changes to the other standard for application assisters that requires compliance with the Exchange's privacy and security standards adopted consistent with § 155.260 (proposed to be redesignated from § 156.1230(a)(2)(ii) to new § 155.415(b)(2)). We also proposed to delete and reserve § 156.1230(a)(2) to reduce redundancies, as QHP issuers subject to the current standards captured at § 156.1230(a)(2) would be subject to the requirements in § 155.415(b) if they elect to use application assisters. We note that any QHP issuers that are not direct enrollment entities, but use application assisters, will also be subject to these requirements and able to use application assisters, to the extent permitted by the applicable Exchange and state law. Finally, consistent with the new paragraphs at § 155.221(c) and (h), we clarified that direct enrollment entities participating in FFEs or SBE–FPs will be permitted to use application assisters, to the extent permitted by state law.

We sought comment on these proposed changes. We are finalizing these amendments as proposed, with technical edits to § 155.415(b)(3) to clarify that the reference at the end of the subparagraph to ''confidentiality and conflicts of interest'' is referring to such standards as are imposed under State law. We further note that HHS will permit application assisters to perform the assistance functions outlined in § 155.415 to assist consumers using the FFEs and SBE–FPs, to the extent allowed under state law, beginning with the 2021 open enrollment period. HHS needs additional time to implement the registration and training processes necessary to operationalize this proposal while maintaining safeguards to protect consumer data and Exchange systems. SBEs that do not rely on the federal platform can implement these provisions sooner, to the extent otherwise permitted under state law. We intend to release future guidance about the form and manner of the registration and training processes under § 155.415(b)(1) for application assisters participating in the FFEs or SBE–FPs.

Comment: Two commenters supported this proposal. Two other commenters questioned whether direct enrollment entity application assisters would be subject to state laws applicable to licensed agents or brokers, such as those pertaining to protecting consumer information, conflicts of interest, and professional liability insurance. Two commenters also suggested direct enrollment entity application assisters should be subject to requirements similar to those for agents or brokers under § 155.220.

Response: We are finalizing this proposal as proposed, with a clarifying edit to § 155.415(b)(3) to clarify that the reference at the end of the subparagraph to ''confidentiality and conflicts of interest'' is referring to such standards as are imposed under state law. We understand that in some states a license may be required for application assisters to assist consumers applying for an eligibility determination or redetermination. We defer to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees as described in this rule, and whether state licensure is required to provide such assistance. If state law requires a license to engage in these activities, then application assisters will need to follow state law for licensure requirements. Since application assisters under the federal definition are not licensed agents or brokers, we do not believe it is appropriate to subject them to the same requirements imposed on licensed agents and brokers under § 155.220. Notably, application assisters are not authorized to function in the same ways as licensed agents or brokers. However, there are some requirements finalized in this rule applicable to application assisters that are similar to those applicable to agents or brokers assisting consumers in the FFEs and SBE–FPs, including requirements to comply with Exchange privacy and security standards. In addition, as described above, application assisters in the FFEs and SBE–FPs will be required to complete registration and training similar to agents or brokers who participate in Exchanges. We will release future guidance about the form and manner for the registration and training processes for application assisters who wish to participate in FFEs and SBE–FPs. Also, as finalized in this rule at § 155.415(b)(3), all application assisters must comply with applicable state law related to the sale, solicitation and negotiation of health insurance products, including any state licensure laws applicable to the functions to be performed by the application assister, as well as applicable state law related to confidentiality and conflicts of interest.

b. Special Enrollment Periods (§ 155.420)

Under our current rules, individuals who are enrolled in employer-sponsored coverage or coverage purchased through an Exchange are eligible for a special enrollment period if they become newly eligible for APTC. However, no comparable special enrollment period exists for individuals who are enrolled in off-Exchange individual market coverage. We believe this may present a significant barrier for some individuals to remain in continuous coverage for the full plan year. Therefore, we proposed to amend § 155.420(d) to add new paragraph (d)(6)(v) to authorize Exchanges, at their option, to provide a special enrollment period to enroll in Exchange coverage for off-Exchange individual market enrollees who experience a decrease in household income and receive a new determination of eligibility for APTC by an Exchange. We proposed to make this special enrollment period available to qualified individuals and their dependents who experience circumstances that result in a decrease in household income if the qualified individual or his or her dependent are both (1) newly determined eligible for APTC by an Exchange, and (2) had MEC in which they were enrolled in and entitled to receive benefits as described in 26 CFR 1.5000A–1(b) for one or more days during the 60 days preceding the change in circumstances. We cite 26

CFR 1.5000A–1(b) because it sets forth criteria for what it means to ''have MEC,'' including general requirements to be enrolled in and entitled to receive benefits under a program or plan identified as MEC under 26 CFR 1.5000A–2 and certain situations under which an individual is not enrolled in MEC but is treated as ''having MEC.'' Under this special enrollment period, qualified individuals and dependents will be eligible for Exchange coverage following the regular prospective coverage effective date rules described in paragraph (b)(1) of this section, and must enroll within 60 days from the date of the financial change, in accordance with paragraph (c)(1) of this section.

We sought to provide individuals with more health coverage options and to empower them to enroll in the health coverage that best meets their needs and the needs of their families. For individuals and families with household incomes greater than 400 percent of the federal poverty level (FPL) who are not eligible for APTC, this may mean that they choose to purchase health insurance coverage outside of the Exchange during the annual open enrollment period or another eligible enrollment period, especially if the market outside of the Exchange offers additional plan options at more affordable prices. However, these individuals or families may experience a change in household income during the benefit year that makes their current health coverage no longer affordable. While paragraphs (d)(6)(iii) and (d)(6)(iv) currently provide special enrollment periods for individuals whose employer-sponsored coverage becomes unaffordable or does not provide minimum value, resulting in the employee becoming newly eligible for APTC, and for individuals previously in the coverage gap who become newly eligible for APTC as a result of a change in household income or move, respectively, there is no current pathway to Exchange coverage for enrollees in off-Exchange individual market plans who are newly eligible for APTC. Since no pathway to Exchange coverage currently exists, we believe that unsubsidized individual market enrollees whose household income has decreased may no longer be able to afford their unsubsidized health plans and may decide to terminate coverage mid-year. Therefore, the special enrollment period in paragraph (d)(6)(v) will address this issue by establishing a pathway to Exchange coverage for qualified individuals enrolled in off-Exchange coverage who experience a decrease in household income and are newly determined eligible for APTC. We believe that this policy will help promote continuous enrollment in health coverage and bring additional stability to the individual market risk pool, which will likely have a positive impact on health insurance premiums.

Individuals seeking to access the special enrollment period will not be current Exchange enrollees and will receive a new determination of eligibility for APTC through the Exchange's consumer application. For the FFEs, an individual's current household income and eligibility for APTC will be verified through the FFE's eligibility system and data matching issue resolution process, in accordance with the requirements in § 155.320(c). To ensure that the special enrollment period is available to the intended population while mitigating risks of adverse selection and inappropriate use, we proposed to require the individual seeking access to the special enrollment period to provide evidence of both a change in household income and of prior health coverage. Verifying that a decrease in household income occurred will prevent individuals who enrolled in health coverage off-Exchange, but have not experienced a financial change, from attempting to use this special enrollment period for the sole purpose of purchasing a more or less comprehensive level of coverage mid-year. To protect the individual market risk pool from adverse selection, as mentioned in this rule, we proposed to include a prior coverage requirement, which will protect against individuals who opted not to enroll in health coverage during the annual open enrollment period from using this special enrollment period to enroll in Exchange coverage mid-year. Additionally, this prior coverage requirement will promote continuous coverage. The prior-coverage requirement aligns with existing prior-coverage requirements for special enrollment periods at § 155.420(d)(2)(i) and (d)(7). We envision leveraging existing pre-enrollment verification procedures [141] to confirm eligibility for the special enrollment period, either through review of an individual's submitted documentation or through use of electronic data sources, when available, prior to sending the individual's plan selection to the issuer for enrollment. Consistent with current practices, in cases where eligibility is not verified electronically, individuals will be required to submit documentation within 30 days of plan selection to verify their prior coverage and their decrease in income. Consumer-submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are currently identified on HealthCare.gov,[142] and we anticipate developing additional consumer instructions relating to submitting documents to verify a decrease in income.

We recognize that State Exchanges maintain flexibility to determine whether and how to implement pre-enrollment verification of eligibility for special enrollment periods and may not have the operational capacity to immediately implement and verify eligibility for this special enrollment period. Some State Exchanges may also determine there is insufficient need among off-Exchange consumers for this special enrollment period because of the rating and pricing practices specific to their state markets. Therefore, we proposed to make this special enrollment period available at the option of the Exchange.

This special enrollment period is intended only for individuals not currently enrolled in Exchange coverage, since current Exchange enrollees who experience a decrease in household income mid-year may already qualify for a special enrollment period under paragraphs (d)(6)(i) and (ii), or may enroll in off-Exchange plans if they become newly ineligible for APTC under § 147.104(b)(2)(i)(B).

Paragraph (a)(4)(iii) of § 155.420 generally limits the plans into which an enrollee who qualifies for a special enrollment period or is adding a dependent through a special enrollment period may enroll. Several special enrollment periods are excluded from this limitation. However, we proposed that the new special enrollment period will be subject to the rule in paragraph (a)(4)(iii). Therefore, should a qualified individual who qualifies for the special enrollment period in paragraph (d)(6)(v) already have members of his or her household enrolled in Exchange coverage and those enrollees do not qualify for another special enrollment period at the same time that provides them with additional plan enrollment flexibilities, the Exchange must allow

[141] Instructions for consumers to verify their eligibility for a special enrollment period are available at *https://www.healthcare.gov/coverage-outside-open-enrollment/confirm-special-enrollment-period/.*

[142] Available at *https://www.healthcare.gov/help/prove-coverage-loss/* and *https://www.healthcare.gov/verify-information/documents-and-deadlines/.*

the qualified individual to be added to the same QHP as the Exchange enrollees in his or her household, if the plan business rules allow. If the plan's business rules do not allow the qualified individual to enroll, the Exchange must allow the current enrollees to change to another QHP within the same level of coverage (or one metal level higher or lower if no such QHP is available), and to add the qualified individual to the same plan as outlined under § 156.140(b). As always, and at the option of the qualified individual, he or she may enroll in a separate QHP at any metal level, in accordance with § 155.420(a)(4)(iii)(B). We anticipate that this situation will arise relatively infrequently due to the availability of the special enrollment periods at (d)(6)(i) and (d)(6)(ii) of § 155.420 for enrollees who become newly eligible for APTC or experience a change in eligibility for cost-sharing reductions.

We also proposed to modify the types of coverage that may satisfy the prior coverage requirement by amending § 155.420(a)(5) to include the coverage types described in paragraphs (d)(1)(iii) and (iv) of this section, such as pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, in addition to MEC described in 26 CFR 1.5000A–1(b). We believe that this clarification is necessary to ensure consistency across our special enrollment period regulations for the types of coverage that qualify an individual for a special enrollment period. We already treat certain types of coverage, including pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, although not independently designated as MEC under 26 CFR 1.5000A–1(b), as MEC for purposes of qualifying for the loss of MEC special enrollment period described in § 155.420(d)(1). However, individuals currently enrolled in these types of coverage will not qualify for special enrollment periods that require prior coverage. To avoid treating the same types of coverage differently for purposes of eligibility for different special enrollment periods, we proposed an aligning edit to paragraph (a)(5).

Lastly, we proposed to clarify certain terms in § 155.420(b)(2)(iv), which addresses the coverage effective dates that apply to the special enrollment periods in § 155.420(d)(1), (d)(3), (d)(6)(iii), (d)(6)(iv), and (d)(7). Specifically, we proposed to replace the word ''consumer'' with the phrase ''qualified individual, enrollee, or dependent, as applicable,'' to align with the terminology used at § 155.420(d) to describe special enrollment period triggering events. We do not anticipate that this wording change will create additional cost or burden for Exchanges or for any other stakeholders.

Comment: We received broad support from commenters for the proposals at § 155.420. Commenters noted the proposed special enrollment period creates consistency with existing special enrollment periods available to individuals who are enrolled in employer-sponsored coverage or coverage purchased through an Exchange who become newly eligible for APTC. Commenters noted the proposed special enrollment period would promote continuous coverage among consumers and increase access to care. We also received comments in support of the modification to prior coverage requirements at § 155.420(a)(5) to include coverage types such as pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, in addition to MEC described in 26 CFR 1.5000A–1(b).

Response: We are finalizing all policies under § 155.420 as proposed. We note that the proposed new special enrollment period under § 155.420(d)(6)(v) is available at the option of the Exchange. HHS is determining the date on which this special enrollment period will be implemented for Federally-facilitated Exchanges and State Exchanges using the federal eligibility and enrollment platform, and anticipates it will not be available until after January 1, 2020.

Comment: One commenter expressed support for the proposed new special enrollment period under § 155.420(d)(6)(v), but urged HHS to reduce the overall number of special enrollment periods to align with the private market and Medicare Advantage program.

Response: HHS is committed to making sure special enrollment periods are available to those who are eligible for them, and equally committed to avoiding any misuse or abuse of special enrollment periods. Recently implemented special enrollment period policies, such as pre-enrollment verification and plan category limitations, are intended to promote continuous enrollment in coverage and protect the risk pool from adverse selection that may have a destabilizing impact on the market for existing enrollees. Given these mitigation strategies, we do not believe it is necessary to reduce the number of available special enrollment periods under § 155.420 at this time.

Comment: Several commenters wrote in support of the proposed requirement that the special enrollment period under proposed § 155.420(d)(6)(v) be available to consumers who were previously enrolled in MEC as defined at 26 CFR 1.5000A–1(b). These commenters wrote that continuous enrollment in comprehensive coverage is important to maintaining a stable risk pool, and expressed concern about adverse selection should the special enrollment period be made available to consumers enrolled in alternate types of coverage such as short-term, limited-duration insurance or health care sharing ministry plans.

Response: We agree that the proposed prior coverage requirement is important to promote continuous coverage and protect against adverse selection, and note that MEC described in 26 CFR 1.5000A–1(b) excludes the coverage types of primary concern to commenters.

Comment: Other commenters stated short-term, limited-duration insurance and other coverage types not currently designated as MEC should be considered to meet the prior coverage requirements for the proposed special enrollment period. Some commenters referenced HHS support for these coverage options in other rulemaking and guidance, and other commenters expressed concern that consumers may be misled into unintentional enrollment into short-term, limited-duration plans.

Response: The Administration seeks to make more coverage options available to consumers, including short-term, limited-duration coverage and other forms of coverage that may not constitute MEC. However, the prior coverage requirements, as implemented in our other special enrollment periods, are intended to promote continuous coverage in MEC and protect the risk pool from adverse selection.

Comment: One commenter suggested we amend the proposed regulatory text to reference prior coverage requirements at § 155.420(a)(5) as opposed to 26 CFR 1.5000A–1(b) to enhance clarity of the prior coverage requirement.

Response: We believe this change, if implemented, would require additional aligning edits for all special enrollment periods containing a prior coverage requirement. We will consider this when making future technical amendments to regulations at § 155.420, but will not make such changes at this time.

Comment: Other commenters stated eligibility for the proposed special enrollment period under § 155.420(d)(6)(v) should be expanded to include consumers who were automatically re-enrolled in either subsidized or unsubsidized health plans which become unaffordable.

Response: Consumers in this scenario may be eligible for the special enrollment period as proposed, provided that they experience a decrease in income and that the plan in which they were automatically re-enrolled meets the current definition of MEC. Consumers automatically re-enrolled into Exchange coverage and who experience a change in eligibility for financial assistance outside the annual open enrollment period may also access the current special enrollment period at § 155.420(d)(6)(i) and (d)(6)(ii).

Comment: Another commenter questioned whether the proposed new special enrollment period under § 155.420(d)(6)(v) should be made available to consumers who experience a change in tax household composition or a resolution of a prior year tax return that causes an individual to become newly eligible for APTC in an Exchange plan.

Response: We believe that many consumers who experience in change in tax household composition may qualify for a special enrollment period under existing regulations, such as in cases of marriage and gaining or becoming a dependent. HHS offered a one-time special enrollment period to consumers who did not enroll in Exchange coverage because they failed to reconcile their APTC on their tax return during the first year of implementation of this requirement. However, we do not believe a permanent extension of this special enrollment period through this proposal is appropriate, as consumers now have multiple years of experience with the requirement that they must file a tax return and reconcile APTC to remain eligible for future APTC. For these reasons, we are finalizing the eligibility requirements for the special enrollment period as proposed and will not expand eligibility as suggested by the commenter.

Comment: Another commenter suggested that consumers should have 90 days, instead of 60 days, to report their financial change to the Exchange.

Response: We believe the current window of 60 days provides ample time for consumers to report triggering events to the Exchange and make authorized plan changes and, in many instances, encourages consumers to avoid extended lapses in health coverage. As a result, we will not increase the time within which consumers must report triggering events to qualify for a special enrollment period.

Comment: Several commenters expressed support for our proposal to require consumers to submit evidence to demonstrate they have experienced a decrease in household income and met the prior coverage requirement. One commenter requested additional information on how these measures would protect against fraud.

Response: We agree that requiring evidence of prior coverage and a decrease in household income are important program integrity measures that protect against fraud. We believe these requirements provide sufficient mitigation against inappropriate use of the proposed special enrollment period.

Comment: Other commenters expressed concern regarding the consumer burden associated with verification requirements and requested more information on what types of consumer documents would be accepted. Another commenter stated that verifying a consumer's decrease in household income creates an undue burden, and that there is no evidence to support the notion that consumers will seek to switch plan category levels mid-year due to health status.

Response: We appreciate that the proposed verification requirements do require consumers to submit documents in most cases. However, our experience with pre-enrollment verification for special enrollment periods demonstrates that consumers are not significantly burdened by these requirements, as the vast majority of special enrollment period applicants who are required to submit documents to complete enrollment are able to successfully verify their eligibility. We maintain that the verification of a consumer's decrease in household income is an important program integrity measure to ensure individual consumers are not able to access this special enrollment period solely due to a change in health status, and are finalizing this verification requirement as proposed. To mitigate consumer burden, we intend to utilize electronic data sources where possible and will leverage existing processes to accept document types that are currently in use by HHS to verify prior coverage and income information.[143]

Comment: Many commenters supported making the proposed special enrollment period at § 155.420(d)(6)(v) at the option of the Exchange. Other commenters urged HHS to require the special enrollment period for all Exchanges and questioned whether HHS would promote the new special enrollment period in its marketing and outreach materials.

Response: We believe State Exchanges are well positioned to assess both the consumer need and the Exchange's operational capacity to implement the proposed special enrollment period and its verification requirements and we are finalizing the proposed special enrollment period at the option of the Exchange. Given the importance of pre-enrollment verification to protecting against adverse selection and misuse of the proposed special enrollment period, we believe requiring the special enrollment period to be implemented by State Exchanges which have not fully implemented pre-enrollment verification may inject adverse risk into the Exchange's marketplace. HHS intends to update current technical assistance and training materials to include information regarding the new special enrollment period and will provide information to relevant stakeholder groups such as issuers, agents and brokers, and consumer assisters.

Comment: Another commenter requested that State Exchanges who rely on the federal eligibility and enrollment platform be granted flexibility to choose to implement the special enrollment period.

Response: HHS intends to implement this special enrollment period for all Exchanges currently using the federal eligibility and enrollment platform, and currently lacks the operational capacity to offer this flexibility.

4. Eligibility Standards for Exemptions (§ 155.605)

a. Eligibility for an Exemption Through the IRS (§ 155.605(e))

Individuals can claim hardship exemptions through the tax filing process for hardships described in § 155.605(e)(1) through (4), which include most hardship exemptions, but not the general hardship types described in paragraph (d)(1) of this section. Allowing the general hardship exemption types to be claimed through the IRS will increase flexibility and decrease burdens for individuals seeking hardship exemptions. Therefore, we proposed to amend § 155.605(e), which describes the exemptions that can be claimed through the IRS tax filing process without an individual having to obtain an exemption certificate number from an Exchange, to add a new paragraph (e)(5) that will allow individuals to claim through the tax filing process hardship exemptions within all of the categories described in paragraph (d)(1) of this section on a federal income tax return

[143] Consumer submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are available at *https://www.healthcare.gov/help/prove-coverage-loss/* and *https://www.healthcare.gov/verify-information/documents-and-deadlines/*, respectively.

for tax year 2018 only. We are finalizing this change as proposed.

This rule aligns with HHS guidance published on September 12, 2018, entitled, ''Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)'' [144] and with IRS Notice 2019–05.[145] We anticipate that the guidance and this rule will provide individuals with additional flexibility for claiming a hardship exemption by providing individuals the additional option of claiming this exemption on their federal income tax return for 2018 only.

Comment: Commenters generally supported the proposal for individuals to claim hardship exemptions on their tax returns without obtaining an exemption certification number from the Marketplace, because it will reduce burden on individuals.

Response: We are finalizing this change as proposed. We agree that this change will lessen the burden on individuals by allowing them to claim the general hardship exemptions through the tax filing process for tax year 2018. It will further reduce burden since individuals will not be required to obtain an exemption certification number from the Marketplace prior to filing their tax returns.

Comment: One commenter stated the proposal was unnecessary given that tax filing season for 2018 returns is underway (this change only applies to the 2018 tax year) and that HHS has not been transparent in the past about the specifications for claiming each type of hardship exemption.

Response: The PPACA grants authority to the Exchanges to grant all exemptions. As a result, HHS has consistently codified in regulations any grant of authority it has provided to the IRS in subregulatory guidance for specific hardship exemptions. And although tax filing season for the 2018 tax year has already begun, HHS plans to maintain our prior practice of providing regulatory revisions when granting authority to the IRS for individuals to claim specific exemptions through the tax filing process. In 2018, HHS published guidance allowing individuals to claim the general hardship exemptions through the IRS on their 2018 tax returns.[146] Also in 2018, we published guidance that provided examples of general hardships that an individual may claim, such as single-issuer county hardships.[147] This guidance did not alter the existing regulations and did not create any new substantive requirements for people seeking a hardship exemption.

Comment: One commenter claimed the proposal undermines the original intent of Congress in enacting the individual mandate by making it too easy for individuals to claim a general hardship exemption.

Response: While we agree that the PPACA's provisions incentivize consumers to obtain health insurance in many respects, the PPACA provides statutory authority for hardship exemptions. Consistent with its authority, HHS seeks to provide individuals with these exemptions in a manner that minimizes burden.

b. Required Contribution Percentage (§ 155.605(d)(2))

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she will be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduces the individual shared responsibility payment to $0 for months beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. The excess of the rate of premium growth over the rate of income growth is also used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.

As discussed elsewhere in this preamble, we proposed as the measure for premium growth a 2020 premium adjustment percentage of 1.2969721275 (or an increase of about 29.7 percent over the period from 2013 to 2019). We are finalizing the new premium growth measure that would be composed of individual market premium growth and employer-sponsored insurance premium growth. Therefore, as noted later in this preamble, we are finalizing a premium adjustment percentage of 1.2895211380 for the 2020 benefit year.[148] This amount reflects an increase of about 3.02 percent over the 2019 premium adjustment percentage (1.2895211380/1.2516634051).

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we will use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, using the National Health Expenditure Account (NHEA) data, the rate of income growth for 2020 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($56,261 for 2019) exceeds per capita PI for 2013 ($44,922), carried out to ten significant digits. The ratio of per capita PI for 2019 over the per capita PI for 2013 is estimated to be 1.2524152976 (that is, per capita income growth of about 25 percent).[149] This reflects an increase of approximately 3.9 percent relative to the increase for 2013 to 2018 (1.2524152976/1.2059028167) used in the 2019 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from federal, state, and local governments (for example, Social Security, Medicare, unemployment

[144] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf.*

[145] *https://www.irs.gov/pub/irs-drop/n-19-05.pdf.*

[146] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf.*

[147] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-Hardship-Exemption-Guidance.pdf.*

[148] Note: As explained in the subsequent footnote, this amount differs from the proposed premium adjustment percentage due to the fact that we utilize the most recent NHEA data, which updated in February 2019.

[149] The 2013 and 2019 per capita personal income figures used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at the following address: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

insurance, workers' compensation, etc.).[150]

Using the 2020 premium adjustment percentage finalized in this final rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2019 is 1.2895211380/1.2524152976, or 1.0296274251. This results in a required contribution percentage of 8.00* 1.0296274251 or 8.24 percent for the 2020 benefit year, which when rounded to the nearest one-hundredth of one percent, represents a decrease of 0.07 of a percentage point from 2019 (8.23702–8.30358).

We also requested comment on whether we should exclude any government transfers (that is, Social Security, Medicare, unemployment insurance, workers' compensation, etc.) from per capita PI, but we did not receive any comments in response to this request.

Comment: Two commenters indicated that they oppose policies that reduce access to health coverage, including the proposed required contribution percentage increases resulting from the proposed change in premium adjustment percentage. Another commenter noted that the proposal would increase the number of individuals who are eligible for catastrophic coverage, which should be adequate to address a patient's needs and thereby not contribute to an expansion of short-term limited duration insurance plans.

Response: HHS is required to update the required contribution percentage annually for purposes of determining whether individuals above the age of 30 qualify for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h). We note that as a result of the updated premium adjustment percentage finalized elsewhere in this rule, the required contribution percentage has decreased. For further discussion of the updated premium adjustment percentage for 2020, refer to section F(3)(e) of this preamble.

F. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Definitions (§ 156.20)

We are defining the term ''generic'' in part 156 in response to comments requesting a definition related to the proposal that amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent not be required to be counted toward the annual limitation on cost sharing. For a discussion of that proposal and the related definition we are finalizing at § 156.20, please see the preamble to § 156.130.

2. FFE and SBE–FP User Fee Rates for the 2020 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25R established federal policy regarding user fees; it specifies that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public. Activities performed by the federal government that do not provide issuers participating in an FFE with a special benefit are not covered by this user fee. As in benefit years 2014 through 2019, issuers seeking to participate in an FFE in the 2020 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2020 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Based on estimated costs, enrollment, and premiums for the 2020 benefit year, we proposed a 2020 benefit year user fee rate for all participating FFE issuers of 3.0 percent of total monthly premiums. This rate is lower than the 3.5 percent FFE user fee rate that we had established for benefit years 2014 through 2019. The lower user fee rate for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We sought comment on this proposal.

As discussed, OMB Circular No. A–25R established federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and federal programs. Accordingly, in § 156.50(c)(2), we specified that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or state instead of direct collection from SBE–FP issuers. The benefits provided to issuers in SBE–FPs by the federal government include use of the federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, as defined at section 1413(e) of the PPACA, and QHP enrollment functions under § 155.400. The user fee rate for SBE–FPs is calculated based on the proportion of user fee eligible FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. Based on this methodology, we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.5 percent of the

[150] U.S Department of Commerce Bureau of Economic Analysis (BEA) Table 3.12 Government Social Benefits. Available at *https://apps.bea.gov/iTable/iTable.cfm?reqid=19&step=3&isuri=1&categories=survey&nipa_table_list=110.*

monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. This rate is lower than the 3.0 percent user fee rate that we had established for benefit year 2019. The lower user fee rate for SBE–FP issuers for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We sought comment on this proposal.

We are finalizing the FFE and SBE–FP user fee rates for the 2020 benefit year at 3.0 and 2.5 percent of monthly premiums, respectively, as proposed.

Comment: The majority of commenters supported HHS' efforts to reduce the costs of operating the FFE and reducing FFE and SBE–FP user fee rates. Some commenters noted HHS should lower the user fee rates further or even eliminate the user fee collection to promote increased competition, improve access to coverage, and reduce issuer duplication of effort in the off-Exchange market. However, other commenters did not support the reduction of FFE and SBE–FP user fee rates, asking that HHS maintain current user fee rates. Several of these commenters encouraged HHS to either re-invest excess funds into consumer outreach and education activities or otherwise restore funding of those activities to 2017 levels. One commenter suggested HHS should use excess funds to support outreach to the uninsured, especially in rural areas. Another commenter noted that increased investments to marketing and outreach will result in lower Exchange premiums due to an improved risk mix, which would outweigh the costs of premium increases from a higher user fee rate. Other commenters noted that HHS needs to ensure that it is investing sufficient funds in improvements to FFE information technology.

Response: We are finalizing the FFE and SBE–FP user fee rates for the 2020 benefit year at 3.0 and 2.5 percent of monthly premiums, respectively, as proposed. We will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE–FPs for future benefit years, and we will establish the user fee rate that is reasonable and necessary to fully fund user fee eligible Exchange operation costs. As we discussed in our proposal to reduce the FEE and SBE–FP user fee rates for the 2020 benefit year, we developed the user fee rates based upon estimated costs, enrollment, and premiums. We specifically noted that the reduced user fee rates, which we are finalizing as proposed, incorporate our estimates of premium increases and enrollment decreases for the 2020 benefit year, and are not solely a reflection of the total expenses estimated to operate and maintain the Federal platform and FFE operations. We also reiterate that any collections in excess of user fee eligible costs for a given year are rolled over for spending to the subsequent year's user fee eligible expenses. Finally, we note that outreach and education efforts will continue to be evaluated annually and funded at the appropriate level. HHS remains committed to providing a seamless enrollment experience for Federal platform consumers. We are committed to applying resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment.

Comment: One commenter noted HHS should further reduce user fees for issuers who take on additional activities administered by the FFE, such as direct enrollment and increased marketing and outreach.

Response: All issuers offering QHPs on the FFEs and SBE–FPs receive the same respective special benefits HHS provides through the activities associated with operating the Federal platform. The amount of special benefits HHS offers issuers does not change even if an issuer chooses to take on additional activities, which may overlap with the Federal platform functions. Further, issuers who choose to participate as an Enhanced Direct Enrollment partner still derive special benefits from costs HHS incurs to operate the Federal platform. As such, our analysis of user fee eligible costs does not justify an additional reduction to the user fee rate beyond what is being finalized in this rule for the 2020 benefit year. We continue to annually review changes in estimated user fee eligible costs due to economies and structural improvements being made to the federal activities that work in concert to improve the enrollment and eligibility determination functions for issuers offering QHPs through FFEs and SBE–FPs, as well as the plan certification activities for FFEs.

Comment: Several commenters requested more transparency from HHS on how we set the FFE and SBE–FP user fee rates and urged HHS to make available a breakdown of Exchange expenses by functional area. Commenters noted more transparency would reduce uncertainty among SBE–FP states, allow states to better ascertain the cost effectiveness of transitioning to a different exchange model, and help identify areas for additional cost savings. One commenter noted HHS should issue a report outlining the use of Exchange user fees for past plan years and annually moving forward. Another commenter noted HHS should provide its specific assumptions for marketing and outreach budget levels through the annual payment notice process. One commenter requested HHS ensure no user fees are diverted to non-Exchange functions and urged HHS to provide refunds or credits to issuers for funds collected in excess of Exchange costs.

Response: The FFE and SBE–FP user fee rates for the 2020 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE–FPs and evaluation of expected enrollment and premiums for the 2020 benefit year. These estimates yielded an FFE user fee rate of 3.0 percent of premiums, and an SBE–FP user fee rate of 2.5 percent of premiums, based on the proportion of FFE functions that apply to SBE–FPs. We expect these user fee rates to result in adequate collections based on our current estimates of enrollment, premiums, and user fee eligible costs.

User fee eligible costs are estimated in advance of the benefit year and are based upon contract costs that are not yet finalized. We will continue to outline user fee eligible functional areas in the Payment Notice, and will evaluate contract activities related to operation of the federal Exchange user fee eligible functions.[151] The categories that are considered user fee eligible include activities that provide special benefits to issuers offering QHPs through the Federal platform, and do not include activities that are provided to all issuers. For example, functions related to risk adjustment program operations, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2020 benefit year), are not included in the FFE or SBE–FP user fee eligible costs. However, costs related to Exchange-related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are incorporated in the FFE user fee eligible costs. SBE–FPs conduct their own health plan reviews and consumer information and outreach, and therefore, the SBE–FP user fee rate is determined

[151] See the following FY2019 budget documents for a reference to estimates provided for the President's budget. HHS FY2019 Budget in Brief. Available at *https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf;* CMS FY2019 Justification of Estimates for Appropriations Committees. Available at *https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2019-CJ-Final.pdf.*

based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE–FPs.

Comment: One commenter noted HHS should lower the SBE–FP user fee rate to 1.5 percent of premiums to better reflect the current stability of the Exchange information technology and outreach and marketing expenses borne by the SBE–FP states, and because HHS likely received excess funds in the 2018 and 2019 benefit years due to the increases in Exchange premiums attributable to the elimination of CSR payments and introduction of silver loading.

Response: The final SBE–FP user fee rate for the 2020 benefit year of 2.5 percent of premiums is based on HHS' calculation of the percent of contract costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We have calculated the total costs allocated to SBE–FP functions and enrollment and premium estimates to yield a user fee rate of 2.5 percent for SBE–FP issuers benefiting from functions provided by the Federal platform. We believe issuers offering QHPs through the Federal platform, either the FFEs or SBE–FPs, should be charged proportionally for the special benefits provided by the Federal platform. As described in this rule, user fee eligible cost estimates are reviewed on an annual basis and developed in advance of the benefit year. If necessary, we will apply an overcollection of user fee funds to user fee eligible expenses in subsequent benefit years, as permissible. As noted in this rule, anticipated Exchange premiums are one factor HHS considers when developing the FFE and SBE–FP user fee rates. HHS agrees that increases in premiums, all other factors being equal, should place downward pressure on the FFE and SBE–FP user rates. Indeed, we are finalizing our proposal to reduce both the FFE and SBE–FP user fee rates by 0.5 percentage points based upon estimates of increased premiums and decreased enrollments for the 2020 benefit year. Although the commenter is correct that HHS reduced its outreach and education costs in 2018 and 2019, we do not charge SBE–FPs for these costs as outreach and education activities are SBE–FPs' responsibility. Therefore any further reduction of outreach and education activities would not be reflected in the SBE–FP user fee rate.

Comment: One commenter requested the user fee rate be charged as a fixed dollar amount instead of a percent of premium because HHS' Exchange costs are fixed.

Response: As we have stated in prior payment notices, the FFE and SBE–FP user fee rates will continue to be assessed as a percent of the monthly premium charged by participating issuers. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the issuer's use of the enrollment and eligibility functions performed by the FFE, and ensures that user fee charges reflect Exchange enrollment.

3. Silver Loading

Section 1402 of the PPACA requires issuers to provide CSRs to help make coverage affordable for certain low- and moderate-income consumers who enroll in silver level QHPs, as well as Indians who enroll in QHPs at any metal level. Section 1402 of the PPACA further states that HHS will reimburse issuers for the cost of providing CSRs. Until October 2017, the federal government relied on the permanent appropriation at 31 U.S.C. 1324 as the source of funds for federal CSR payments to issuers. However, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides an appropriation. In response to the termination of CSR payments to issuers, many issuers increased premiums in 2018 and 2019 only on silver level QHPs to compensate for the cost of CSRs—a practice sometimes referred to as ''silver loading'' or ''actuarial loading.'' Because premium tax credits are generally calculated based on the second-lowest cost silver plan offered through the Exchange, this practice has led to consumers receiving higher premium tax credits. The cost of these higher premium tax credits are being borne by taxpayers.

Silver loading is the result of Congress not appropriating funds to pay CSRs, with the result being an increase to the premiums of benchmark plans used to calculate premium tax credits, and the federal deficit.[152] The Administration supports a legislative solution that would appropriate CSR payments and end silver loading.[153] In the absence of Congressional action, we sought comment on ways in which HHS might address silver loading, for potential action in future rulemaking applicable not sooner than plan year 2021. Consistent with our discussion in the proposed rule, we are not finalizing any change in policy for silver loading in this final rule.

Comment: All commenters supported silver loading as an option to maintain consumer affordability and participation. The majority of commenters urged HHS to continue to allow states to determine how to implement CSR loading. Some commenters expressed opposition to the practice of ''broad loading,'' in which issuers increase premiums on all metal level plans (on- and off- Exchange) to mitigate the lack of CSR reimbursement. Those commenters stated that increasing premiums for all plans would force unsubsidized consumers to pay higher premiums and would decrease APTC amounts. Commenters noted the reduction in financial assistance, and large premium swings from year to year will cause consumer confusion and instability in the Exchanges, and such market disruption may lead to issuers leaving the Exchanges.

Some commenters suggested that HHS should phase in a limitation on silver loading after permanent and stable funding is provided, to mitigate significant out-of-pocket costs for eligible enrollees who would see the amount of their premium tax credit reduced.

Response: We appreciate the comments received and will take them into consideration in determining whether future action is appropriate.

4. Essential Health Benefits Package

a. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

In the 2019 Payment Notice, we finalized options for states to select new EHB-benchmark plans starting with the 2020 benefit year. Under § 156.111, a state may modify its EHB-benchmark plan by:

152 CBO estimates that, under current law, outlays for health insurance subsidies and related spending will rise by about 60 percent over the projection period, increasing from $58 billion in 2018 to $91 billion by 2028. See CBO report *The Budget and Economic Outlook: 2018 to 2028,* April 2018, page 51. Available at *https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53651-outlook.pdf.*

153 The President's Fiscal Year 2020 Budget includes a legislative proposal to provide for a mandatory appropriation to make CSR payments for calendar year 2020. The proposal also allows for CSR payments to issuers who did not ''silver-load'' or ''broad-load'' from the 4th quarter of 2017 through the end of 2019.

(1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year;

(2) Replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017 plan year; or

(3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark plan.

Under any of these three options, the EHB-benchmark plan will also have to meet additional standards, including scope of benefits requirements. These options were intended to provide states with more flexibility in the selection of their EHB-benchmark plan than had previously existed. In the 2019 Payment Notice, we encouraged states to consider the potential impact on vulnerable populations as they select their new EHB-benchmark plans, and the need to educate consumers on benefit design changes. We also remind states to inform issuers of such changes should they select a new EHB-benchmark plan.

In the proposed rule, we stated that we believe that the three new options—the third in particular—may provide states with additional flexibility to address the opioid epidemic. For example, Illinois made changes to its EHB-benchmark plan for plan year 2020 that aim to reduce opioid addiction and overdose by including in its EHB-benchmark plan alternative therapies for chronic pain, restricting access to prescription opioids, and expanded coverage of mental health and substance use disorder treatment and services.[154] We continue to encourage other states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic.

Additionally, the 2019 Payment Notice stated that we would propose subsequent EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. Accordingly, we proposed May 6, 2019 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2021 plan year. We noted that this deadline would be delayed, if necessary, to be on or after the effective date of this final rule. To give advance notice to states and issuers, we simultaneously proposed May 8, 2020 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2022 plan year. Although not a requirement, we recommend states submit applications at least 30 days prior to the submission deadlines to ensure completion of their documents by the proposed deadlines. We recognize that these deadlines are earlier in the year than the July 2, 2018 deadline for the state's EHB-benchmark plan selection for the 2020 plan year. These deadlines would allow for an earlier finalization of a state's EHB-benchmark plan and a longer time period for issuers to develop plans that adhere to their state's new EHB-benchmark plan. States would have to have completed the required public comment period and submit a complete application by the deadlines.

Comment: We received a number of comments supporting our encouragement of states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic. Some commenters supported such modifications, but only to the extent they do not impose strict limits on the doses of opioids for treating pain, which commenters stated could come at the expense of individuals who need access to these medications to treat their conditions.

Response: We appreciate these comments, and continue to urge states to consider taking all appropriate action to address the opioid epidemic, including by making modifications to their EHB-benchmark plans.

Comment: Several commenters supported the EHB-benchmark selection submission deadline as proposed. A few commenters expressed their desire for HHS to extend the submission deadline to allow states more time to evaluate their EHB-benchmark plans, and consider submitting changes to HHS.

Response: We are finalizing May 6, 2019 as the 2021 plan year EHB-benchmark plan selection submission deadline and May 8, 2020 as the 2022 plan year EHB-benchmark plan submission deadline, as proposed. We recognize the proposed submission deadline for plan year 2021 is earlier in the year than the deadline for the previous plan year and also before the rule's effective date. However, unlike the 2020 submission deadline, which we finalized in the 2019 Payment Notice concurrently with the policy at § 156.111(a), we are not finalizing any new policy at § 156.111(a) for 2021. Because states have now had over a year to determine whether to make EHB-benchmark plan changes for 2021, we believe that the deadline gives them ample time to submit the required documents to HHS and that they have been preparing for this deadline since proposed in the proposed rule. In having an earlier submission date than for the 2020 plan year, issuers and other stakeholders would have more time to understand benchmark plan changes made by the state and for issuers to design plans that will comply with changes to the benchmark. We do not believe that finalizing a later date, including a date on or after the rule's effective date, would give issuers sufficient time to design plans.

b. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we also finalized a policy through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadlines applicable to state selection of a new benchmark plan would also apply to this state opt-in process. We therefore proposed May 6, 2019 as the deadline for states to notify us that they wish to permit between-category substitution for the 2021 plan year and May 8, 2020 as the deadline for states to notify us that they wish to permit between-category substitution for the 2022 plan year. We noted that the 2021 plan year deadline would be delayed, if necessary, to be on or after the effective date of this final rule. States wishing to make such an election must do so via the EHB Plan Management Community.

Comment: A few commenters supported the proposed submission deadline.

Response: We are finalizing the submission deadlines as proposed. The deadline for the 2021 plan year is May 6, 2019, and the deadline for the 2022 plan year is May 8, 2020. Although the 2021 plan year deadline is before the rule's effective date, we believe that this is necessary in order for issuers to have sufficient time to design plans that take into account any benefit substitution changes.

c. Prescription Drug Benefits (§ 156.122)

i. Mid-Year Formulary Change Reporting Requirement

At new § 156.122(d)(3), we proposed that for plan years beginning on or after January 1, 2020, QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the proposed changes to § 147.106(e). QHP issuers in the FFEs would be required to report the name of the drug being removed from the formulary, dosage, name of the generic equivalent, the Rx Norm Concept Unique Identifier

[154] IL DOI Press Release, ''Illinois becomes first and only state to change Essential Health Benefit-benchmark plan,'' Aug. 27, 2018. Available at *https://www2.illinois.gov/IISNews/18098-DOI_Essential_Health_Benefit-benchmark_plan_Release.pdf.*

(RxCUI) associated with the brand and generic drug, if the brand drug was moved to a higher cost sharing tier or removed from the formulary, in a manner specified in the forthcoming PRA associated with this final rule. We proposed to use this information to understand how the proposed change would affect QHP enrollees. We sought comment on this proposal.

Comment: Several commenters supported the collection as proposed. Other commenters suggested expanding the submission to require issuers to report to mid-yearly formulary changes to the state in addition to HHS. Other issuers suggested HHS use existing data sources to collect the information.

Response: We are not finalizing this collection because we are not finalizing the proposal in this rule at § 147.106(e). For more information about that proposal, see the preamble to § 147.106.

ii. Therapeutic Substitution

We solicited comments on two additional drug policies intended to consider the potential of therapeutic substitution. First, the prescription drug market became more efficient after several states passed laws that allowed for generic substitution. Similarly, therapeutic substitution, which consists of substituting chemically different compounds within the same class for one another,[155] could be employed to improve the efficiency of the pharmaceutical market. We acknowledged that many stakeholders are opposed to therapeutic substitution and that there are concerns regarding efficacy, adverse effects, drug interactions, and different indications for drugs within a class. If therapeutic substitution were to become commonplace, efficient systems that allow for seamless communication among prescribers, pharmacies, and insurance companies would need to be in place. Therapeutic substitution may help decrease drug costs if it can be implemented in a way that does not negatively affect quality and access to care. We solicited comment on whether therapeutic substitution and generic substitution policies should both be pursued since each of the two options might offset any potential premium impact of the other, as well as whether certain drug categories and classes are better suited to therapeutic substitution than others. We also sought comment on any existing standards of practice for therapeutic substitution and whether those standards are nationally recognized and readily available for providers to use.

Second, the majority of issuers, employers, and pharmacy benefit managers negotiate price discounts and rebates from pharmaceutical manufacturers by implementing tiered formularies, which link patients' cost-sharing obligations to the list price of each drug. Tiered formularies have been successful in attenuating the growth in pharmaceutical spending and overall drug spending. However, in recent years, drug spending has again increased. Reference-based pricing is one strategy for attenuating increases in pharmaceutical spending. Reference-based drug pricing occurs when an issuer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price.[156] Implementation of reference-based pricing for drugs could bring down overall health plan costs, and perhaps premium increases, while increasing consumer out-of-pocket costs in some instances. Durable medical equipment benefits like eyeglasses and contacts are sometimes covered in a similar manner. Although reference-based pricing is often discussed in the context of network adequacy and using certain providers within a particular network who are willing to accept a reference price, we do not intend for this drug policy to have network implications, and issuers are currently free to impose lower cost sharing for drugs obtained via mail order. We sought comment on the opportunities and risks of implementing or incentivizing reference-based pricing for prescription drugs.

Comment: Some commenters did not support the implementation of a policy related to therapeutic substitution due to concerns regarding efficacy, adverse effects, drug interactions, different indications for drugs within a class and the potential of such a policy to jeopardize consumers' access to clinically indicated drugs. Commenters noted that automatic therapeutic substitution overrides a treatment decision made between the patient and provider, which could put patients' health at risk. Additionally, commenters noted that they did not believe that the current health care system possesses the operational capacity to implement therapeutic substitution without jeopardizing the quality of and access to care. Commenters who were supportive of therapeutic substitution stated they appreciated HHS' efforts to allow additional tools and flexibility to manage drug costs and recommended that biosimilars and interchangeable biologics be therapeutically substitutable as well.

One commenter supported the concept of reference-based pricing, but noted that implementation must be carefully considered. Commenters who opposed reference-based pricing stated they were not confident that there were transparency measures in place to enable reference-based pricing to be successful.

Two commenters requested that HHS postpone its consideration of implementing reference-based pricing until greater transparency is achieved throughout the entire pharmaceutical supply chain. One commenter noted that if HHS were to implement reference-based pricing, it should allow patients to request an exception from the balance billing requirement if a medication is medically necessary but exceeds the reference price. Two commenters were receptive to a policy related to reference-based pricing, noting that implementation could have a positive impact on pharmacy spending, but cautioned that because this type of pricing model may be somewhat new in the pharmacy space, it could initially cause member confusion. Some commenters cautioned that implementation of this initiative would require extensive member communication. Additionally, one commenter noted that HHS should study the various ways group benefit plans are already employing reference-based pricing before acting on regulatory requirements or incentives and cautioned against defining reference-based pricing explicitly before actually engaging in any formal regulatory activity concerning this practice, as premature definitions can be limiting.

Response: We appreciate these comments and will take them under consideration for any future rulemaking.

d. Prohibition on Discrimination (§ 156.125)

Opioid misuse and addiction is a serious national crisis that affects public health, as well as social and economic welfare. More than 115 people in the United States die each day from opioid

[155] Pengxiang, L., Sanford Shwartz, J., & Doshi, J.A. (2016). Impact of Cost Sharing on Therapeutic Substitution: The Story of Statins in 2006. Journal of the American Heart Association.

[156] Robinson, J.C, Whaley, C.M., & Brown, T.T. (2017). Association of Reference Pricing with Drug Selection and Spending. New England Journal of Medicine, 377:658665. Doi:10.1065/NEJMsa1700087.

overdoses.[157] The Centers for Disease Control and Prevention estimates that the total costs of prescription opioid misuse alone in the United States is $78.5 billion per year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.[158] It has been an active Public Health Emergency, as determined by the Secretary under 42 U.S.C. 247d, since October 26, 2017.[159]

Several factors have influenced the opioid crisis, including: the opioid pharmaceutical manufacturing and supply chain industry; deficient patient and provider pain management education; rogue pharmacies and unethical physician prescribing; and the insufficient availability of treatment services, including Medication-Assisted Treatment (MAT).[160]

MAT is the use of medication approved by the FDA for addiction detoxification, relapse prevention, or maintenance treatment, in combination with counseling and behavioral therapies to treat substance use disorders and prevent overdose through detoxification, relapse prevention, and maintenance treatment.[161] MAT has proven to be clinically effective in treating opioid use disorder and to significantly reduce the need for inpatient detoxification services for individuals with opioid use disorder.[162]

Despite this evidence, and despite the attention paid to the nationwide opioid Public Health Emergency, there is not comprehensive, nationwide coverage of the drugs used in MAT, at least among QHP issuers. A review of QHP issuer formularies in the 39 FFE and SBE–FP states for which we have data reveals that, while many QHPs cover all four MAT drugs, not all do. Specifically, for plan year 2018, 2,553 QHPs (95 percent) in these 39 FFE and SBE–FP states cover all four of these drugs; 105 QHPs (4 percent) cover three; and 25 QHPs (<1 percent) cover two. Given the effectiveness of MAT and the severity of the nationwide opioid Public Health Emergency, we encourage every health insurance plan to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all four MAT drugs on a formulary. In the proposed rule, we encouraged issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and destigmatizing its use.[163]

In addition, we stated that we have become aware that a MAT drug's inclusion on a formulary does not necessarily ensure coverage of that drug when administered for MAT. We stated that we are aware that some issuers utilize plan designs which exclude coverage of certain drugs when used for MAT while the same drugs are covered for other medically necessary purposes, such as analgesia or alcohol use disorder. Under § 156.125, which implements the provision prohibiting discrimination, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

We reminded issuers that any indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices is potentially discriminatory. As is the case for any EHB, issuers are expected to impose limitations and exclusions on the coverage of benefits to treat opioid use disorder, including the drugs used for MAT or any associated benefit such as counseling or drug screenings, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. If a plan excludes certain treatment of opioid use disorder, but covers the same treatment for other medically necessary purposes, the issuer must be able to justify such an exclusion with supporting documentation explaining how such a plan design is not discriminatory.

We noted that a similar standard is imposed under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (section 2726 of the PHS Act).[164] Under regulations implementing the EHB requirements,[165] the requirements of MHPAEA are extended to issuers of non-grandfathered health insurance coverage in the individual and small group markets, both on and off the Exchange. Under HHS regulations at § 146.136 implementing MHPAEA, if a drug is offered under a plan for treatment of a medical condition or surgical procedures but is excluded for MAT purposes to treat a substance use disorder, that is considered to be a nonquantitative treatment limitation.[166] A nonquantitative treatment limitation cannot be imposed on mental health or substance use disorder benefits in any classification [167] unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards or other factors used in applying the limitation to the mental health or substance use disorder

[157] CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. *https://wonder.cdc.gov.*

[158] Florence C.S., Zhou C., Luo F., Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Med Care. 2016; 54(10):901–906. doi:10.1097/MLR.0000000000000625. Available at *https://www.ncbi.nlm.nih.gov/pubmed/27623005.*

[159] As determined by Acting Secretary Eric D. Hargan. ''Determination that a Public Health Emergency Exists''. October 26, 2017. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx.* Renewed by Acting Secretary Hargan. ''Renewal of Determination that a Public Health Emergency Exists''. January 19, 2018. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-24Jan2018.aspx.* Renewed by Secretary Alex M. Azar II. ''Renewal of Determination that a Public Health Emergency Exists''. April 20, 2018. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx.* Renewed by Secretary Azar. ''Renewal of Determination that a Public Health Emergency Exists''. July 19, 2018. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19July2018.aspx.* Renewed by Secretary Azar. ''Renewal of Determination that a Public Health Emergency Exists''. October 18, 2018. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-18Oct2018-aspx.aspx.* Renewed by Secretary Azar. ''Renewal of Determination that a Public Health Emergency Exists''. January 17, 2019. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-17jan2019.aspx.*

[160] ''The President's Commission on Combating Drug Addiction and the Opioid Crisis''. Pages 19–23. November 1, 2017. Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[161] There are four drugs currently used in MAT: Buprenorphine; naltrexone; buprenorphine in combination with naloxone; and methadone.

[162] ''Medication and Counseling Treatment''. September 28, 2015. Available at *https://www.samhsa.gov/medication-assisted-treatment/treatment.*

[163] ''For many people struggling with addiction, failing to offer MAT is like trying to treat an infection without antibiotics . . . We know that there is sometimes stigma associated with MAT—especially with long term therapy. But someone on MAT, even one who requires long-term treatment, is not an addict. They need medicine to return to work; re-engage with their families; and regain the dignity that comes with being in control of their lives. These outcomes are literally the opposite of how we define addiction. Our fellow citizens who commit to treatment should not be treated as pariahs—they are role models.'' Azar, Alex. Plenary Address to National Governors Association, February 24, 2018. Available at *https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.*

[164] MHPAEA originally applied to large group health plans and large group health insurance coverage, and PPACA extended it to apply to individual health insurance coverage.

[165] § 156.115(a)(3).

[166] For examples of nonquantitative treatment limitations, see § 146.136(c)(4)(ii).

[167] Classifications under MHPAEA are as follows: Inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs. § 146.136(c)(2)(ii).

benefits in the classification are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards and other factors used in applying the limitation to medical/surgical benefits in the same classification. In other words, the issuer must demonstrate that, as written and in operation, the processes, strategies, evidentiary standards, and other factors it applied in deciding that the drug is covered for medical/surgical purposes, are comparable to those it used in deciding that the drug is not covered for MAT purposes, and that there are no separate limitations that apply only for mental health or substance use disorder benefits.[168]

We also noted that federal civil rights laws, such as title II of the Americans with Disabilities Act and section 504 of the Rehabilitation Act, prohibit discrimination against individuals who participate in or have completed substance use disorder treatment, including MAT.

Comment: Many commenters supported our continued interpretation of the prohibition on discrimination as it applies to the coverage of treatments for opioid use disorder. Many commenters supported our recommendation that issuers provide comprehensive coverage of MAT, thereby increasing access to MAT and destigmatizing its use. Several commenters suggested that HHS require coverage of all four drugs used in MAT, and a few commenters cautioned against such a requirement.

A number of comments outside the scope of this rule encouraged HHS and states to take aggressive enforcement actions against all discriminatory benefit designs, including plan designs that may violate MHPAEA. A number of commenters suggested that discriminatory benefit designs exist with regards to women's health benefits and benefits for the treatment of sexually transmitted diseases.

Response: We appreciate these comments and will take them under consideration as we continue to monitor and implement strategies to address discriminatory benefit designs and the opioid epidemic.

e. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the PPACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in the PPACA: (1) The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters. To calculate the premium adjustment percentage for the 2020 benefit year, we calculate the percentage by which the average per capita premium for health insurance coverage for 2019 exceeds the average per capita premium for health insurance for 2013, and round the resulting percentage to 10 significant digits. The resulting premium index reflects cumulative, historic growth in premiums from 2013 onwards.

The 2015 Payment Notice (79 FR 13743) and 2015 Market Standards Rule (79 FR 30240) established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond. Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which are calculated by the CMS Office of the Actuary. In the proposed 2015 Payment Notice, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums. Based on comments received, we finalized the 2015 Payment Notice to instead use per enrollee employer-sponsored insurance premiums in the methodology for calculating the premium adjustment percentage. We chose employer-sponsored insurance premiums because they reflected trends in health care costs without being skewed by individual market premium fluctuations resulting from the early years of implementation of the PPACA market reforms. We adopted this methodology in subsequent Payment Notices for 2016 through 2019, but noted in the 2015 Payment Notice that we may propose to change our methodology after the initial years of implementation of the market reforms, once the premium trend is more stable.

As discussed in the 2015 Payment Notice, we considered four criteria when finalizing the premium adjustment percentage methodology for the 2015 benefit year: (1) Comprehensiveness—the premium adjustment percentage should be calculated based on the average per capita premium for health insurance coverage for the entire market, including the individual and group markets, and both fully insured and self-insured group health plans; (2) Availability—the data underlying the calculation should be available by the summer of the year that is prior to the calendar year so that the premium adjustment percentage can be published in the annual HHS notice of benefit and payment parameters in time for issuers to develop their plan designs; (3) Transparency—the methodology for estimating the average premium should be easily understandable and predictable; and (4) Accuracy—the methodology should have a record of accurately estimating average premiums. We continue to consider these criteria as we evaluate other sources of premium data that could be used in calculating the premium adjustment percentage.

To date, the NHEA projections of per enrollee employer-sponsored insurance premiums have also been used by the Department of the Treasury and the IRS for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.[169] The applicable percentage in section 36B(b)(3)(A) of the Code is used to determine the amount an individual must contribute to the cost of an Exchange QHP and thus, relates to the amount of the individual's premium tax credit. This is because, in general, an individual's premium tax credit is the lesser of (1) the premiums paid for the Exchange QHP, and (2) the excess of the premium for the benchmark plan over the contribution amount. The contribution amount is the product of the individual's household income and the applicable percentage.

The required contribution percentage in section 36B(c)(2)(C) of the Code is used to determine whether an offer of employer-sponsored insurance is considered affordable for an individual, which relates to eligibility for the premium tax credit because an individual with an offer of affordable employer-sponsored insurance that

[168] See § 146.136(c)(4)(iii), Ex. 10.

[169] IRS Rev. Proc. 2014–37.

provides minimum value is ineligible for the premium tax credit. Specifically, an offer of employer-sponsored insurance is considered affordable for an individual if the employee's required contribution for employer-sponsored insurance is less than or equal to the required contribution percentage (set at 9.5 percent in 2014) of the individual's household income.[170]

Section 36B(b)(3)(A)(ii) of the Code generally provides that the applicable percentages are to be adjusted after 2014 to reflect the excess of the rate of premium growth over the rate of income growth for the preceding year. Section 36B(c)(2)(C) of the Code provides that the required contribution percentage is to be adjusted after 2014 in the same manner as the applicable percentages are adjusted in section 36B(b)(3)(A)(ii) of the Code. As noted in this rule, the Department of the Treasury and the IRS have issued guidance providing that the rate of premium growth for purposes of these section 36B provisions is based on per enrollee spending for employer-sponsored insurance as published in the NHEA.[171]

In the proposed rule, we proposed to modify the premium growth measure that we used to calculate the premium adjustment percentage for the 2020 benefit year and beyond. We proposed to use a more comprehensive premium measure that captures increases across the market, including individual market premiums and employer-sponsored insurance premiums, for purposes of calculating the premium adjustment percentage. Specifically, we proposed to calculate the premium growth measures for 2013 and 2019 as private health insurance premiums minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees.

This premium measure is an adjusted private individual and group market health insurance premium measure, which is similar to NHEA's private health insurance premium measure. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance, ''direct purchase insurance,'' which includes individual market health insurance purchased directly by consumers from health insurance issuers, both on and off the Exchanges, and Medigap insurance, and the medical portion of accident insurance (''property and casualty'' insurance). The measure we proposed to use is published by NHEA and includes NHEA estimates and projections of employer-sponsored insurance and direct purchase insurance premiums, but we proposed to exclude Medigap and property and casualty insurance from the premium measure since these types of coverage are not considered primary medical coverage for individuals who elect to enroll. We proposed to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) so that the premium growth measure more closely reflects premium trends for all individuals primarily covered in the private health insurance market since 2013, and we anticipated that the proposed change to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) would additionally reduce federal premium tax credit expenditures, if the Department of the Treasury and the IRS were to adopt the proposed change.

Using the private health insurance premium measure (excluding Medigap and property and casualty insurance), we proposed that the premium adjustment percentage for 2020 be the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2019 (when proposed, $6,468) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (when proposed, $4,987).[172] Using this formula, the proposed premium adjustment percentage for the 2020 benefit year was 1.2969721275 ($6,468/$4,987), which represented an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 29.7 percent over the period from 2013 to 2019.

We are finalizing the proposal to use per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) in the premium adjustment percentage calculation. As we discussed in the proposed rule, immediate application of this change will result in a faster premium growth rate for the foreseeable future than if we continued to use only employer-sponsored insurance premiums as in prior benefit years. We anticipate that this change will have several impacts on the health insurance market. As explained in this rule, the premium adjustment percentage is used to set the rate of increase for the maximum annual limitation on cost sharing, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code. Accordingly, a premium adjustment percentage that reflects a faster premium growth rate would result in a higher maximum annual limitation on cost sharing, a higher required contribution percentage, and higher employer shared responsibility payment amounts than if the current premium adjustment percentage premium measure (employer-sponsored insurance only) were adopted for the 2020 benefit year.

In the proposed rule, we stated that, if we finalize a change to the premium measure used in the premium adjustment percentage for the 2020 benefit year, we expect the Department of the Treasury and the IRS to issue additional guidance to adopt the same premium measure for purposes of future indexing of the applicable percentage and required contribution percentage under section 36B of the Code. Additionally, the Health Insurance Providers Fee established under section 9010 of the PPACA also takes the measure of premium growth used for the applicable percentage in section 36B(b)(3)(A)(ii) of the Code into consideration for purposes of calculating the fee for 2019 and beyond.[173] We expect the Department of the Treasury and the IRS to adopt the premium measure that results in a faster premium growth rate that we are

[170] See also IRS Notice 2015–87, Q&A 12 for discussion of the adjustment of the required contribution percentage as applied for certain purposes under sections 4980H and 6056 of the Code.

[171] See IRS Rev. Proc. 2014–37 (*https://www.irs.gov/pub/irs-drop/rp-14-37.pdf*).

[172] The 2013 and 2019 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

[173] See PPACA section 9010(e)(2). However, under section 4003 of Public Law 115–120, Division D—Suspension of Certain Health-Related Taxes, enacted on January 22, 2018, the collection of the Health Insurance Providers Fee is suspended for the 2019 calendar year.

finalizing, which will result in slightly higher Health Insurance Providers Fees imposed on health insurance issuers that are required to pay the fee, over the long term. We anticipate that health insurance issuers subject to the Health Insurance Providers Fee generally would pass the fee on to consumers, and that higher fees would increase premiums in the individual, small, and large group markets, although we anticipate that any premium increases would be very small. Additionally, as stated in the proposed rule, a faster premium growth measure and corresponding increase in the applicable percentage will increase the amount that individuals receiving the premium tax credit contribute towards premiums, thereby reducing federal outlays for the premium tax credit that had increased significantly in the 2018 benefit year as many issuers increased silver plan premiums to offset the cost of providing cost-sharing reductions to eligible enrollees without receiving cost-sharing reduction payments from the federal government.

We have updated the impact estimates in the Regulatory Impact Analysis of this final rule to reflect impact estimates provided by the Department of the Treasury, pending their anticipated adoption of the premium measure finalized in this rule.

Although commenters expressed concern about the impacts resulting from this change, as discussed later in the preamble of this final rule, we are finalizing the change as proposed—to use per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) as the premium growth measure for purposes of calculating the premium adjustment percentage. This approach allows us to achieve the statutory and regulatory goals of a more comprehensive and accurate measure of premium costs across the private market.

Using the proposed premium measure, the premium adjustment percentage is calculated as the difference between the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2019 ($6,436) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 ($4,991), carried out to 10 significant digits.[174] Using this formula, the final premium adjustment percentage for 2020, rounded to 10 significant digits, using per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) is 1.2895211380 ($6,436/$4,991), which is an increase of approximately 29 percent over the period from 2013 to 2019.

Comment: All commenters on this topic expressed opposition to or concerns about the proposed change, many of whom indicated HHS should continue to use the current measure, employer-sponsored insurance premiums, to measure premium growth. Almost all commenters were concerned about the impact of the proposal on the health insurance market and individuals and families, citing HHS' estimates of the impacts in the Regulatory Impact Analysis, including a decrease in enrollment and increase in premiums and out-of-pocket costs for consumers.

Several commenters noted that individual market premiums should not be used to measure premium growth since 2013 because premiums have increased due to PPACA market reforms and federal policy and legislative changes, including changes in the composition of the individual market risk pool that occurred with the elimination of pre-existing condition exclusions, the inclusion of a richer benefit package and lower cost-sharing than typically provided in the individual market in 2013, the cessation of CSR payments, the reduction of the individual shared responsibility penalty to $0, and the ending of the reinsurance program. Commenters stated these premium increases should not be included in the measure of premium growth because they are not based on utilization or cost of medical services.

Several commenters noted our methodology is flawed because the proposal starts with 2013 as the base year, but the indexing provisions of section 1401 of the PPACA start with ''the calendar year after 2014'' (2015) and then use the preceding year, or 2014 as the base year. They state that since EHB did not go into effect until 2014, utilizing a base year earlier than 2014 does not compare the prices of like individual insurance products. Several commenters recommended HHS use a base year no earlier than 2018 (rather than 2013) to avoid inclusion of premium increases resulting from PPACA market reforms and other federal policy and legislative decisions. Some commenters noted that HHS considered and rejected adopting using individual market premiums in the premium measure for the premium adjustment percentage for the 2015 benefit year because the premium trend was not stable, and the premium trend is still not stable, citing the PPACA policy and legislative changes mentioned in this rule and that 2019 is the first year new rules have taken effect regarding short-term, limited-duration insurance (STLDI) plans and association health plans (AHP), which may further disrupt the market and increase premiums. One commenter recommended only using individual market premium increases for underlying medical trends (in other words, not including premium increases resulting from federal policy and legislative changes), while a few commenters indicated that the change is not statutorily required, and urged HHS to delay the change until the premium trend is more stable.

Several commenters stated HHS's justification provided for this change is inadequate and contrary to the legislative intent of the financial assistance structure of the PPACA. One commenter noted that the primary purpose of providing APTC to Exchange enrollees is so that the federal government, rather than low-income individuals and families, bears the burden of any premium increases in the individual market. A few commenters urged HHS to consider other ways to reduce federal expenditures, or to focus on efforts at lowering the overall cost of health care, rather than placing the burden on households. One commenter supported keeping federal costs reasonable, but was concerned about HHS doing so by way of reducing PTC to consumers, which will increase the number of uninsured individuals. Another commenter noted that while the proposed change will result in federal PTC savings (a decreased taxpayer burden), consumers receiving APTC are taxpayers, and that the negative effects of reducing their APTC would outweigh the benefits of lower tax burden.

Another commenter noted that the proposed change will impact the coverage ''affordability'' percentages

[174] The 2013 and 2019 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

that IRS releases each spring, which are used by applicable large employers to determine the affordability of their offers of coverage for purposes of the employer shared responsibility provisions. As such, the commenter urged HHS to work closely with the IRS on the timing of any change and recognize that employer plans rely on the timely release of this data each spring for their annual plan-development processes.

Response: As stated earlier in this preamble, we are finalizing our proposal to calculate the premium adjustment percentage using a measure of premium growth that accounts for individual market health insurance premiums, as well as employer-sponsored insurance. Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The purpose of this index is to measure growth in premiums, and the statute gives HHS flexibility to determine how to measure premium growth. Because the individual market is much smaller than the group market,[175] the increase in the percentage amount due to the change in methodology from measuring growth only in employer-sponsored insurance to using the new measure, which includes individual market health insurance, is quite small. Under the employer-sponsored insurance measure, the premium adjustment percentage would have been 1.2551737602. As stated above, under the new premium measure, the premium adjustment percentage is 1.2895211380, or a difference of approximately 3.4 percentage points. Therefore the new premium measure does not result in a significantly larger premium adjustment percentage; however, it does more comprehensively reflect the actual growth in premiums in the insurance markets.

As stated in the 2015 Payment Notice, we previously excluded premiums from the individual market because they were most affected by the significant changes in benefit design and market composition in the early years of implementation of the PPACA market rules and were most likely to be subject to risk premium pricing. However, the PPACA is now past the initial years of implementation and issuers have had the opportunity to collect data on the risk composition of the individual market and adjust pricing accordingly. We have concluded, based on the general trend of stabilizing average premiums in the individual market,[176] that the likelihood of risk premium pricing has decreased. We further believe that individual market premium increases going forward will more accurately reflect true premium growth, thereby addressing the bases we identified in the 2015 Payment Notice for excluding individual market premiums from the premium adjustment percentage calculation. Therefore, we are finalizing our proposal to measure growth of premiums issuers charged enrollees more comprehensively, by no longer excluding individual market premiums.

While the PPACA does contain financial assistance provisions that shift costs from consumers to the federal government as noted by commenters, it also requires the Secretary to measure premium growth, so that the effects of premium growth can be reflected in other payment parameters. As such, although we are sensitive to commenters' concerns about the potential impact on consumers, we continue to believe that a premium growth measure that affects cost-sharing and payment parameters in the employer group markets and individual health insurance market should comprehensively reflect premium growth in all affected markets, and should not be limited to employer-sponsored insurance growth. In effect, this change is a technical correction for measuring premium growth, as the previous exclusion of individual market data was not the most comprehensive method of premium growth measurement, but was deemed necessary as a result of the premium instability in the individual market immediately following implementation of the PPACA market reforms.

Additionally, while we recognize comments noting that recipients of PTC are also taxpayers, reducing federal expenditures is not strictly a benefit to the federal government, but to all taxpayers, which includes those who are not PTC recipients. Further, we understand that the premium adjustment percentage is relevant to determine the affordability of plans offered by applicable large employers for purposes of the employer shared responsibility provisions. We will continue to work closely with the Department of the Treasury and the IRS to timely release information on the indexing of the various PPACA provisions.

With respect to the comments requesting we use a different base year, the applicable statute, section 1302(c)(4) of the PPACA, requires the Secretary of HHS to establish a premium adjustment percentage that measures premium growth between the preceding calendar year (2019, in this case) and 2013. It is not legally permissible to change the base year to any year other than 2013, including the base year reflected in the PPACA section cited by commenters, section 1401.

Comment: Many commenters opposed the proposed change and indicated HHS should continue to use the current premium measure; however, a few of these commenters stated if HHS does adopt the proposed change it should change some aspects of its approach. A few commenters recommended that HHS consider a delayed or gradual phase in of individual market premiums over several years.

Response: As noted earlier in this section of the preamble, we believe that the growth of average premiums in the individual market has stabilized, and the reasons for excluding individual market premiums from the premium adjustment percentage calculation have been addressed.[177] Although we considered a phase-in approach, we do not believe that further delay meets the statutory and regulatory goals of using a comprehensive measure of premium growth. Additionally, as stated above, we believe that the individual market is now sufficiently stable to justify the immediate inclusion of individual market premium growth in the indexing measure going forward. For example, in plan year 2019, premiums for the second lowest cost silver plan decreased 2 percent, the first decrease in that premium measure since the advent of the PPACA.[178] As such, we believe it is appropriate to prioritize better achieving the goals of comprehensiveness and accuracy of the premium adjustment percentage methodology over the limited effect on mitigating impacts that implementing our proposal using a

[175] Note for example the differences in enrollment between Employer-sponsored Insurance and Direct Purchase reflected in Table 17 of the ''NHE Projections 2018–2027—Tables'' available in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* In 2020, the Office of the Actuary projects Employer-sponsored Insurance enrollment will be 176.6 million, and Direct Purchase enrollment will be 21.3 million.

[176] *ASPE Research Brief: 2019 Health Plan Choice and Premiums in Healthcare.gov States,* showing a decrease in silver plan premiums for plan year 2019, available at *https://aspe.hhs.gov/system/files/pdf/260041/2019LandscapeBrief.pdf.*

[177] *See id.*

[178] *Id.*

phased-in approach would be likely to have.

Comment: One commenter provided a detailed explanation about what they viewed to be legal deficiencies with our statutory analysis, our justification for the proposed change, and the procedural approach. One commenter indicated that HHS has underestimated the significance of the proposed change's impact on the Health Insurance Providers Fee and the increased premiums in the commercial and Medicare markets that may result from the proposed change.

One commenter expressed that the proposed change will be doubly punitive to its state residents because as part of the state's market stabilization efforts, residents are subjected to a penalty for not carrying insurance. Additionally, the commenter noted that states that developed section 1332 waivers will be unduly penalized by this change because it will result in a reduction of premium tax credits. Another commenter noted that if more states implement section 1332 waivers, then a premium adjustment percentage that incorporates individual market premium changes would also reflect the impact of these waivers (that is, reduced individual market premiums) and could result in additional federal expenditures on premium tax credits through reduced required contributions. The commenter noted there could be challenges for states seeking new waivers to reflect the impact of this consideration when evaluating compliance with the deficit neutrality guardrail and the available amount of federal pass-through funding in their waiver applications.

Response: We believe that section 1302(c)(4) of the PPACA provides the Secretary of HHS with the authority to update and modify the premium adjustment percentage and premium growth rate measure, and that our proposal was within this authority. While we recognize that any reductions to federal PTC spending could reduce the pass-through amounts that are available to states that implement State Relief and Empowerment Waivers under section 1332 of the PPACA, those reductions in pass-through payments would be consistent with the reduction in the federal savings attributable to such waivers. Additionally, as noted in the regulatory impact section of this rule, we are aware that, if adopted by the Department of the Treasury and the IRS, this change in premium measures will likely have the effect of raising premiums, and we understand that such increases could have additional consequences for consumers in states where they may be penalized for not carrying insurance. As explained in responses to other comments on this proposal, we believe these impacts are outweighed by the goals of achieving comprehensive and accurate calculations of premium growth. We will continue to consider possibilities for appropriate modifications to the calculation of the premium adjustment percentage that reflect the changing health insurance markets, and we will consider these and other comments as we develop future policy in this area.

Based on the final 2020 premium adjustment percentage, we are finalizing the following cost-sharing parameters for benefit year 2020.

Maximum Annual Limitation on Cost Sharing for Plan Year 2020

Under § 156.130(a)(2), for the 2020 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2020. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of $50.

In the proposed rule, we proposed that the 2020 maximum annual limitation on cost sharing would be $8,200 for self-only coverage and $16,400 for other than self-only coverage, based on the previously proposed premium adjustment percentage of 1.2969721275 for 2020, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013.[179] As stated in this rule, we are finalizing the change in premium measure used to calculate the premium adjustment percentage as proposed, and thus the final premium adjustment percentage for the 2020 benefit year is 1.2895211380. Based on this premium adjustment percentage, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, the final 2020 maximum annual limitation on cost sharing will be $8,150 for self-only coverage ($6,350 * 1.2895211380 = $8,188.46; rounded down to the next lowest multiple of 50 dollars is $8,150) and $16,300 ($8,150 * 2) for other than self-only coverage. This represents an approximately 3.16 percent increase above the 2019 parameters of $7,900 for self-only coverage and $15,800 for other than self-only coverage.

[179] See *http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

Comment: Several commenters expressed opposition to the increased maximum annual limitation on cost-sharing. Many commenters stated that they oppose the proposed change in premium measure for the premium adjustment percentage in part because of the effect it would have of further increasing the maximum annual limitation on cost-sharing for individuals and families. Multiple commenters suggested that if the premium adjustment percentage is not finalized as proposed, given the timing of the final rule, issuers should be allowed a safe harbor to use the proposed maximum annual limitation on cost-sharing for 2020. One commenter requested HHS lower the burden of out-of-pocket costs for patients or keep current cost-sharing limits at 2019 levels. Another commenter supported the flexibility to increase the out-of-pocket maximum to a higher limit and requested that HHS coordinate with the IRS in setting the maximum out-of-pocket limits for HSA-eligible HDHPs so they match.

Response: We recognize commenters' concerns about the burden that an increase in the maximum annual limitation on cost-sharing places on consumers who meet the annual limit. However, the indexing of this parameter is required under section 1302(c)(1)(B) of the PPACA, and does not permit HHS to postpone updates to these parameters for the applicable benefit year. Therefore, we are finalizing the 2020 maximum annual limitation on cost sharing of $8,150 for self-only coverage and $16,300 for other than self-only coverage, based on the premium adjustment percentage for the 2020 benefit year that is finalized in this rule. With regard to the maximum out-of-pocket limit that applies for purposes of HSA-eligible HDHPs, annual adjustments are determined under section 223(g) of the Code, which by statute provides a different annual adjustment than the annual adjustment provided under section 1302(c) of PPACA. Further, we note that the Department of the Treasury and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs under section 223 of the Code.

f. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver-level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in part 156, subpart E, we

specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver-plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we proposed to continue to use the method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations.

As discussed in this rule, the finalized 2020 maximum annual limitation on cost sharing will be $8,150 for self-only coverage and $16,300 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. In this rule, we describe our analysis for the 2020 plan year and our proposed results.

Consistent with our analysis in the Payment Notices for 2014 through 2019, we developed three test silver-level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2020 maximum annual limitation on cost sharing for self-only coverage ($8,200). The test plan designs are based on data collected for 2019 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2020, the test silver-level QHPs included a PPO with typical cost-sharing structure ($8,200 annual limitation on cost sharing, $2,575 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing ($5,250 annual limitation on cost sharing, $3,500 deductible, and 20 percent in-network coinsurance rate); and an HMO ($8,200 annual limitation on cost sharing, $4,300 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: $500 inpatient stay per day, $500 emergency department visit, $25 primary care office visit, and $55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2020 AV Calculator and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent of FPL (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (⅔ reduction), will not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), will cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½, consistent with the approach taken for benefit years 2017 through 2019. We further proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of FPL be reduced by approximately ⅔, as specified in the statute, and as shown in Table 9. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three test QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute will not reduce the benefit afforded to enrollees in the aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level.

We tested again using the numbers based on the final premium adjustment percentage, which are reflected below, and arrived at the same conclusions. We are therefore not considering any changes to the level of the reductions at this time.

In prior years we found, and we continue to find, that for individuals with household incomes of 250 to 400 percent of FPL, without any change in other forms of cost sharing, any reduction in the maximum annual limitation on cost sharing will cause an increase in AV that exceeds the maximum 70 percent level in the statute. As a result, we did not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of FPL.

We note that for 2020, as described in § 156.135(d), states are permitted to submit for approval by HHS state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2018 deadline.

TABLE 9—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2020

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2020	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2020
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (100–150 percent of FPL)	$2,700	$5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (151–200 percent of FPL)	2,700	5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (201–250 percent of FPL)	6,500	13,000

Comment: One commenter noted that the proposal to reduce the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL by approximately ⅕, rather than ½, consistent with the approach taken for benefit years 2017 through 2019, hurts their members. The commenter recommended that HHS rescind its plan to go through with these regulatory changes and asks that the Administration continue to support legislation to appropriate CSR funding.

Response: We share the commenter's concern about the impact of a smaller reduction in cost-sharing on individuals with a household income between 200–250 percent of FPL. We will continue to monitor plan AV and benefit design in future years for impact on premiums and out-of-pocket costs. We are finalizing the reductions with modifications to reflect the final premium adjustment percentage and maximum annual limitation on cost-sharing.

g. Application to Cost-Sharing Requirements and Annual and Lifetime Dollar Limitations (§ 156.130)

We proposed several policy changes to cost-sharing requirements, including a policy change as to what is included as EHB, which would affect the annual out-of-pocket limitation under PHS Act section 2707(b) and the annual and lifetime dollar limit prohibition under PHS Act section 2711. Although large group market coverage and self-insured group health plans are not required to cover all EHB, non-grandfathered group health plans and health insurance issuers are subject to PHS Act section 2707(b), and all group health plans and group health insurance issuers are subject to PHS Act section 2711, which are incorporated by reference in the Employee Retirement Income Security Act of 1974 (ERISA) and the Code.[180] To comply with those sections, such plans and issuers must choose a definition of EHB to determine which benefits are subject to the annual out-of-pocket limitation and the prohibition on lifetime and annual dollar limits.[181] Therefore, these proposals were relevant to, and would apply to, all health coverage and plans.

i. Cost-Sharing Requirements for Generic Drugs

In 2014, the Departments of Labor, HHS, and the Treasury [182] (the tri-departments) released an FAQ on the treatment by large group market health insurance issuers and self-insured group health plans, with regard to the annual out-of-pocket limitation, of an individual's out-of-pocket costs for a brand drug when a generic equivalent is available and medically appropriate. Because large group market health insurance issuers and self-insured group health plans are not required to offer EHB, the FAQ states that such plans may include only generic drugs, if medically appropriate (as determined by the individual's personal physician) and available as EHB, while providing a separate option (not as part of EHB) of selecting a brand drug at a higher cost-sharing amount, as non-EHB. Thus, such plans could choose not to count toward the annual limit on cost sharing some or all of the amounts paid toward the brand drugs that are not EHB, if the participant or beneficiary selects a brand name prescription drug in circumstances in which a generic was available and medically appropriate (as determined by the individual's personal physician).[183]

The FAQ also states that for non-grandfathered health plans in the individual and small group markets that must provide coverage of EHB, additional requirements apply.[184] This reflects the implementation of the EHB requirements as implemented in the Patient Protection and Affordable Care Act (PPACA); Standards Related to Essential Health Benefits, Actuarial Value and Accreditation; Final Rule (EHB Final Rule),[185] in which we stated that plans are permitted to go beyond the number of drugs offered by the EHB-benchmark plan without exceeding EHB. We further clarified in the 2016 Payment Notice that, if the plan is covering drugs beyond the number of drugs covered by the EHB-benchmark plan, all of these drugs are EHB and cost sharing paid for the drugs must count toward the annual limitation on cost sharing.[186]

Given the increase in the cost of prescription drugs, and particularly brand drugs, in the proposed rule, we stated that HHS believes additional flexibility is needed for health plans in the individual and small group markets that must provide coverage of the EHB to encourage consumers to use more cost effective generic drugs. We proposed, subject to applicable state law, to allow a plan that covers both a brand prescription drug and its generic equivalent, for plan years beginning on or after January 1, 2020, to consider the brand drug to not be EHB, if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is determined to be required under an exception process at § 156.122(c).

Under such circumstances, if an enrollee purchases the brand drug when the generic equivalent was available and medically appropriate, we proposed that the issuer would be permitted to not count the difference in cost sharing between that which is paid for the brand drug and that which would be paid for the generic equivalent drug toward the annual limitation on cost sharing under § 156.130, but would still be required to attribute the cost sharing that would have been paid for the generic equivalent toward the annual limitation on cost sharing under § 156.130. This would maintain a balance between incentivizing the use of lower-cost drugs and the consumer protection provided by the annual limitation on cost sharing.

We further proposed that for a plan to do so, the plan must have an exception process in place in accordance with § 156.122(c) for the enrollee to request coverage of the brand drug.

[180] Sections 2707(b) and 2711 of the PHS Act apply the annual cost-sharing limitation on EHBs and the prohibition on annual dollar limits on EHBs to non-grandfathered non-federal governmental group health plans of all sizes, and by implication, to large group health insurance issuers through which such plan provide coverage. Additionally, section 715 of ERISA and section 9815 of the Code incorporates those provisions by reference, applying them to non-grandfathered privately sponsored group health plans and their health insurance issuers in the small and large group markets.

[181] Generally, for this purpose, a group health plan or health insurance issuer that is not required to provide EHB must define such benefits in a manner that is consistent with—(1) one of the EHB-benchmark plans applicable in a state under § 156.110, and including any additional required benefits that are considered EHB under § 155.170(a)(2) or (2) one of the three Federal Employees Health Benefits Program plan options as defined by § 156.100(a)(3), supplemented, as necessary, to meet the standards in § 156.110. For more information regarding the application of the PHS Act section 2711 to group health plans and issuers, see the Departments implementing regulations at 26 CFR 54.9815–2711, 29 CRF 2590.715–2711, and § 147.126.

[182] FAQs About Affordable Care Act Implementation (Part XIX). May 2, 2014. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.* This FAQ remains in effect for large group market and self-insured group health plans despite the fact that the related proposed policy for the individual and small group markets is not being finalized.

[183] In determining whether a generic is medically appropriate, the FAQ provides that a plan may use a reasonable exception process. For example, the plan may defer to the recommendation of an individual's personal physician, or it may offer an exceptions process meeting the requirements of § 156.122(c).

[184] For example, these plans have to meet the EHB drug count standard at § 156.122(a) that sets a minimum threshold for drug coverage and while the drug count standard is based on chemically distinct drugs, these plans have to consider other factors in establishing their prescription drug benefit.

[185] 78 FR 12834, 12845 (February 25, 2013).

[186] 80 FR 10817.

If finalized, this interpretation would have permitted all group health plans and group health insurance issuers to impose lifetime and annual dollar limits on such brand drugs because they would no longer be considered EHB and not be subject to the prohibition on such limits.

HHS also considered an alternate proposal, under which an issuer would have been permitted to except the entire amount paid by a patient for a brand drug for which there is a medically appropriate generic alternative from the annual limitation on cost sharing at § 156.130. Because this alternate proposal also relied on an interpretation of what is considered EHB, the alternate proposal would have also applied to non-grandfathered group health plans and health insurance issuers subject to the annual limit on cost-sharing provision under PHS Act 2707(b), and in ERISA section 715 and Code section 9815.

We proposed that these changes to the annual limitations on cost sharing would be effective starting with the 2020 plan year. We solicited comments on these alternatives, both of which we proposed to apply to group health plans, group health insurance coverage, and individual market coverage, regardless of whether they are required to cover EHBs.

An issuer taking advantage of this proposed flexibility would be excluding the brand drug from coverage as EHB. Therefore, the issuer also could have imposed annual or lifetime dollar limits on coverage of the brand drug under those circumstances. Additionally, PTC (and APTC) could not be applied to any portion of the premium attributable to coverage of brand name drugs not covered as EHB, so issuers of QHPs would be required to calculate that portion of QHPs' premiums and report it to the applicable Exchange.

We also solicited comments on any limitation on group health plans' and health insurance issuers' information technology systems being able to accumulate the cost sharing consistent with this policy, whether this proposed policy should be subject to or preempt any state law regarding the application of cost sharing between the generic and branded version of a drug that would prevent the application of this proposed policy, and whether an issuer not attributing cost-sharing to the annual limitation on cost sharing under this approach should be considered an adverse coverage determination and subject to the coverage appeals processes under § 147.136.

Finally, we sought comment regarding whether we should *require,* instead of permit, issuers to exclude brand drugs from being EHB if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is determined to be required under the exception process under 156.122(c), and to exclude the cost sharing for the brand name drug from accumulating toward the annual limitation on cost sharing according to one of the proposed alternatives.

Comment: A few commenters supported the policy as proposed. Several commenters suggested that we not finalize this policy due to the administrative cost and burden of implementing the policy, and the potentially harmful consequences for those with chronic medical conditions. Several commenters also expressed concern about being able to implement the policy for the 2020 plan year. Many commenters noted the proposal would increase out-of-pocket expenses for enrollees. Some commenters expressed concern regarding the policies' impact on actuarial values, which are based on EHB for certain plans. Other commenters were not in favor of the alternative proposal due to the complexity and administrative burden of determining cost sharing under the proposal. Commenters also stated that plans and issuers already encourage enrollees to use generic drugs, and that the proposed policy is unnecessary and undermines the definition of EHB. There were several comments requesting clarification of the term ''generic drug.'' A few commenters stated that the proposed policy should be optional for issuers.

Response: In light of commenters' concerns about the complexity of implementing this proposal, we are not finalizing this proposal at this time, and will continue to review the points raised by commenters.

ii. Cost-Sharing Requirements and Drug Manufacturers' Coupons

Drug manufacturers often offer coupons to patients to reduce patient out-of-pocket costs. Drug manufacturers may offer these coupons for various reasons: To compete with another brand name drug in the same therapeutic class, to compete with a generic equivalent when released, or to assist consumers whose drug costs would otherwise be extremely high due to a rare or costly condition.[187] Some states prohibit the use of such coupons if a generic alternative is available.[188]

We recognize that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients. However, the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true costs of drugs. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs.

The Administration has identified high and rising out-of-pocket costs for prescription drugs, among other issues, as a challenge to consumers. In some cases, manufacturer coupons may be increasing overall drug costs and can lead to unnecessary spending by issuers, which is passed on to all patients in the form of increased premiums and reduced coverage of other potentially useful health care interventions. While the PPACA does not speak directly to the accounting and use of drug manufacturer coupons to the annual limitation on cost sharing, we believe that the overall intent of the law was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee. The proliferation of drug coupons supports higher cost brand drugs when generic alternatives are available which in turn supports higher drug prices and increased costs to all Americans and for other federal health programs.

For these reasons, at new § 156.130(h)(2), we proposed, for plan years beginning on or after January 1, 2020, notwithstanding any other provision of the annual limitation on cost sharing regulation, that amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost sharing. Not counting such amounts toward the annual limitation

[187] Van Nuys, K., Joyce, G., Ribero, R., & Goldman, D.P. (2018). A Perspective on Prescription Drug Copayment Coupons. Los Angeles, CA: Leonard D. Schaeffer Center for Health Policy & Economics.

[188] For example, see, *https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175H/Section3.*

on cost sharing would promote: (1) Prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market.

We noted that this proposal, which is permissive, would also apply to non-grandfathered group health plans, to which the annual out-of-pocket limitation applies under PHS Act section 2707(b) as incorporated into the Code and ERISA.

We sought comment on this proposal and whether states should be able to decide how coupons are treated. Additionally, we sought comment on whether it would be difficult for issuers to carve out direct support offered by drug manufacturers from their calculation of enrollees' payments toward their annual limitation on cost sharing, and to carve out exceptions (for when a generic equivalent is not available, for example), when cost sharing paid by direct support offered by drug manufacturers will be counted toward the annual limitation on cost sharing, including whether information technology systems could be easily updated for this purpose. We also sought comment on issuers' ability to differentiate between drug manufacturer coupons and other drug coupons, whether their information technology systems would need modifications to make such differentiation, what a reasonable implementation date would be if implementation barriers exist, and how drug discount programs (as opposed to coupons) should be treated under this proposal. Finally, we sought comment regarding whether this policy should be limited to QHPs only.

We are finalizing the policy as proposed, subject to the modifications discussed in the following responses to comments and a non-substantive grammatical correction. In addition, for consistency with the terminology currently used in § 156.130, we are making a non-substantive modification to the finalized regulatory text from ''insured patients'' to ''enrollees''. This modification is not intended to reflect a change in policy. Under this final rule, issuers are permitted to utilize this policy only to the extent permissible by applicable state law.

Comment: Many commenters supported HHS' proposal. Some commenters recommended that all manufacturer support for cost sharing that is provided directly to the patient be excluded from the annual limitation on cost sharing, not just for brand drugs where generic equivalents are available. Several commenters recommended that HHS update the policy so that enrollees who indicate they may need a brand-name drug qualify for the appeals process in § 147.136 or the drug exception process under § 156.122(c). These commenters stated that if enrollees are found to require a brand-name drug, the issuer should be required to count brand drug coupons for that enrollee toward their cost-sharing limits. Some commenters also noted that coupon and discount programs are not transparent and recommended that HHS should standardize them to make their financial aspects more visible to pharmacies and issuers for purposes of implementing this proposal.

Response: We appreciate the important considerations raised by commenters, in particular regarding the exclusion of all manufacturer support for cost sharing that is provided directly to the patients from the annual limitation on cost sharing. As noted in the proposed rule, this policy is intended to address the distortion in the market caused when consumers choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. Therefore, the final regulation limits the discretion to exclude manufacturer coupons from counting towards the annual limitation on cost sharing for specific prescription brand drugs that have a generic equivalent, as the availability of a coupon may cause physicians and patients to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. Where there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market. Similarly, when an enrollee is determined through an appeals process in § 147.136 or the drug exception process under § 156.122(c) to require a brand drug because the generic or other alternative may not be available or medically appropriate, the use of the manufacturer coupon would not disincentivize a less expensive choice. Therefore, under those circumstances, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing. We have added language to the regulation text to address this clarification.

We believe that standardizing drug manufacturer coupon and discount programs is outside the scope of this rulemaking. We will consider these and other comments as we develop future policy in this area.

Comment: Some commenters were concerned that explicitly allowing an issuer to not count certain third-party payments towards the annual limitation on cost sharing is contrary to the PPACA. They expressed concerns that the proposal would increase out-of-pocket costs for certain patients with serious conditions, make medically necessary medication less affordable and accessible for them, and jeopardize their health because they find it more difficult to adhere to their drug regimen.

Response: We recognize commenters' concerns about the burden associated with the exclusion of manufacturer coupons from counting towards the deductible and annual limitation on cost sharing for specific prescription brand drugs that have a generic equivalent. However, the availability of a coupon may cause physicians and patients to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative are available. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs.

Comment: Some commenters requested that HHS clarify the term ''generic equivalent.'' One commenter suggested the proposed rule be limited to situations where the generic drug is rated as a therapeutic equivalent to the branded drug under the FDA Orange Book. Another commenter stated that the term ''generic equivalent'' was too broad and failed to reference the FDA's process of testing and approving generic drugs for use by consumers.

Response: We intended our proposal to refer to the term ''generic equivalent'' under a commonly understood meaning. Generic drugs primarily are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA). Therefore, in response to comments, we are finalizing regulation text to define ''generic'' for this purpose by reference to the FDCA. This definition is consistent with the definition of generic used for the Medicare Prescription Drug Benefit.[189]

Comment: Several commenters were concerned that these changes should be permissive, but not required for plans and issuers. They highlighted that issuers may have difficulty in identifying when a coupon is used by enrollees to purchase drugs at a retail pharmacy. It may take issuers time to implement operational systems to track use of coupons.

[189] 42 CFR 423.4.

Response: We recognize commenters' concerns that use of these coupons may be difficult to track. Under the regulation, issuers may, but are not required to, undertake the option to exclude manufacturer coupons from counting towards the annual limitation on cost sharing.

Comment: Several commenters noted that the final language should expressly provide that these limitations on coverage only apply to the extent consistent with state law.

Response: In response to comments, we clarify that the ability to exclude amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent from being counted toward the annual limitation on cost sharing is subject to applicable state law. This means that states can require that such amounts be counted toward the annual limit on cost sharing. We are modifying the final regulation text to state this explicitly.

5. Segregation of Funds for Abortion Services (§ 156.280)

At § 156.280(c)(3), we proposed that, beginning with plan year 2020, if a QHP issuer provides coverage of non-Hyde abortion services [190] in one or more QHPs, the QHP issuer must also offer at least one ''mirror QHP'' that omits coverage of non-Hyde abortion services throughout each service area in which it offers QHP coverage through the Exchange, to the extent permissible under state law. We proposed that a ''mirror QHP'' provide identical benefit coverage to one of the QHPs with non-Hyde abortion coverage, with the exception of the inclusion of the coverage of non-Hyde abortion services. We received over 25,000 comments on this proposal, and are in the process of reviewing them. As we are still reviewing the comments, we are not able to finalize this proposal in the timeframe necessary to ensure that issuers are able to implement such a change before the opening of the QHP certification application window for the 2020 benefit year. We may finalize it in a future rulemaking. If we finalize this provision in future rulemaking, it would not take effect sooner than the 2021 benefit year.

6. Quality Standards (§§ 156.1120, 156.1125, 156.1130)

Regulatory reform and reducing regulatory burden are high priorities for us. To lower health care costs, enhance patient care, and reduce the regulatory burden on the health care industry, including for health plan issuers and the providers who deliver services through their plans, in October 2017, we launched the Meaningful Measures Initiative.[191] This initiative is one component of our agency-wide Patients Over Paperwork Initiative.[192]

The Meaningful Measures Framework is a strategic tool for putting patients over paperwork by identifying the highest priority areas for quality measurement and quality improvement, to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. This initiative is a new approach to quality measures that will foster operational efficiencies that include decreasing data collection and reporting burden while focusing on quality measurement aligned with meaningful outcomes.

By including Meaningful Measures in our quality reporting and quality improvement programs such as the Quality Rating System, QHP Enrollee Experience Survey and the Quality Improvement Strategy, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We encourage QHP issuers to use performance measures aligned with the Meaningful Measures Initiative in fulfilling their certification requirement to implement a Quality Improvement Strategy that provides increased reimbursement or other market-based incentives for improving health outcomes of plan enrollees.

In addition, we will continue to assess quality measures in our programs including the Quality Rating System and the QHP Enrollee Experience Survey, to ensure that we are using a parsimonious set of the most meaningful measures for patients, clinicians, and health plans in those quality programs. If we propose any changes or removal of measures, we will include those for public comment in the Annual Call Letter for the QRS and QHP Enrollee Survey,[193] as well as address potential changes to information collection requirements to comply with the Paperwork Reduction Act.

Comment: Several commenters supported quality standards across the Exchanges, as well as the Meaningful Measures initiative to help streamline measures across quality reporting and quality improvement programs. One commenter recommended the stratification of quality measures by race, ethnicity, language, socioeconomic status, sex, gender identity, sexual orientation, disability, and other demographic factors and that we prioritize the inclusion of disparities-sensitive and health equity measures in the Meaningful Measures areas across domains. Some commenters mentioned that quality activities, such as the Quality Rating System and the QHP Enrollee Survey, empower consumers, promote high value care and are critical functions of an Exchange. Some commenters urged transparency of both price and quality data to help consumers choose high quality care.

Response: We did not propose updates to the Quality Rating System, QHP Enrollee Survey or Quality Improvement System regulations in the proposed rule. We appreciate the comments and will take them into consideration as we continue implementing CMS quality reporting programs such as the Quality Rating System, QHP Enrollee Survey and Quality Improvement Strategy.

7. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

As described in the preamble to §§ 155.220, 155.221, and 155.415, we proposed significant changes to these regulations to streamline and consolidate the requirements applicable to all direct enrollment entities—both QHP issuers and web-brokers. To reflect these changes, we also proposed conforming changes in § 156.1230(a)(2)

[190] The Hyde Amendment as currently in effect permits federal funds to be used for abortions only in the limited cases of rape, incest, or if a woman suffers from a life-threatening physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, as certified by a physician. It further prohibits the use of federal funds for health benefits coverage that includes coverage of abortions in instances beyond those limited circumstances. In this rule, those services falling outside the scope of the Hyde Amendment are ''non-Hyde abortion services.''

[191] ''Meaningful Measures Hub.'' May 5, 2018. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[192] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

[193] Final 2018 Call Letter for the QRS and QHP Enrollee Survey. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/2018-QRS-Call-Letter_July2018.pdf.*

and (b). We proposed to amend § 156.1230(b) to add a new paragraph (b)(1) that will require issuers participating in direct enrollment to comply with the applicable requirements in § 155.221. We also proposed to delete and reserve paragraph (a)(2) of § 156.1230 to reduce redundancies in light of the proposed changes to § 155.415. We did not receive any comments specific to the proposed changes to § 156.1230 and are finalizing these changes as proposed. For a more thorough discussion of these changes, please see the preamble to §§ 155.220, 155.221, and 155.415.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 11. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[194] Table 10 in this final rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 10—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES *

Occupation title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
All Occupations	00–0000	$24.34	$24.34	$48.68

* Note that only the occupations related to the ICRs being finalized are included in the table.

B. ICRs Regarding Risk Adjustment Data Validation Exemptions (§ 153.630(g))

In this final rule, we are codifying § 153.630(g)(3), under which an issuer will be exempt from risk adjustment data validation, beginning with the 2018 benefit year of risk adjustment data validation, if an issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that the issuer meets certain requirements. To qualify for this exemption, the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual who can legally and financially bind the issuer. To qualify for the exemption, an issuer also could not have been a positive error rate outlier in the prior benefit year's risk adjustment data validation. We continue to anticipate that fewer than 10 issuers will submit this information to HHS annually. Under 5 CFR 1320.3(c)(4), this ICR will not be subject to the PRA, as it will affect fewer than 10 entities in a 12-month period.

We are finalizing the proposal to codify at § 153.630(g)(1) and (2) two exemptions for certain issuers from risk adjustment data validation that were finalized in the 2018 and 2019 Payment Notices. The reduction in burden for issuers who meet the criteria to be exempted under proposed § 153.630(g)(1) and (2) was estimated in those rules, and have been incorporated into OMB Control Number 0938–1155 (CMS–10401—''Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment). Codifying these policies as part of HHS regulations as finalized in this rulemaking will not affect current burden estimates.

C. ICRs Regarding Agent or Broker Termination and Web Broker Data Collection (§ 155.220)

We are finalizing the requirement at § 155.220(c)(4)(i)(A), for web-brokers to provide HHS a list of agents or brokers that by contract or other arrangement use the web-broker's website to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form and manner to be specified by HHS. Currently, § 155.220(c)(4)(i)(A) requires the provision of this information if requested by HHS. The burden on a web-broker to comply with this requirement is covered by the information collection currently approved under OMB control number 0938–1349 (CMS–10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities).

We are finalizing the provision at § 155.220(g)(3)(ii), to allow HHS to immediately terminate an agent's or broker's agreement(s) with the FFEs for cause with notice if an agent or broker fails to comply with the requirement to maintain the appropriate licensure in every state in which the agent or broker actively assists consumers with enrolling in QHPs on the FFEs or SBE–FPs. An agent or broker whose agreement(s) with the FFEs are immediately terminated for cause under

[194] See May 2017 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_nat.htm.*

the new proposed paragraph (g)(3)(ii) will be able to request reconsideration under § 155.220(h). Although the process to request reconsideration imposes a small burden on agents or brokers subjected to terminations, we anticipate fewer than 10 terminations annually under this new authority. Under 5 CFR 1320.3(c)(4), this ICR will not be subject to the PRA as we anticipate it will affect fewer than 10 entities in a 12-month period.

We are finalizing the proposal at § 155.220(m)(3), that the Exchange may collect from a web-broker during its registration with the Exchange under § 155.220(d)(1) or at another time on an annual basis, in a form and manner specified by HHS, information sufficient to identify the individuals who comprise the entity's corporate leadership or ownership, as well as any corporate or business relationships with other entities that may seek to register with the FFE as a web-broker. We believe the burden on a web-broker to comply with these requirements is covered by the information collection currently approved under OMB control number 0938–1349 (CMS–10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities). In the supporting statement for that information collection, we stated web-brokers will also be required to provide other documentation as requested in response to emerging compliance issues, for HHS to monitor compliance. The information we proposed to collect based on proposed § 155.220(m)(3) is the type of information we anticipated when we referenced other documentation in response to emerging compliance issues.

D. ICRs Regarding Direct Enrollment Entity Standardized Disclaimer (§ 155.221)

We are finalizing the proposed provision at § 155.221(b)(2) to require direct enrollment entities (both QHP issuers and web-brokers) to prominently display a standardized disclaimer, in the form and manner provided by HHS, to assist consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs during a single shopping experience. HHS will provide the exact text for this disclaimer and the language will not need to be customized. As described in the preamble, we will provide further information on the text and other display details for the standardized disclaimer in guidance. At that time, we will estimate the burden associated with this requirement, solicit public comment, and request OMB approval in accordance with the PRA, as may be necessary.

E. ICRs Regarding Special Enrollment Periods (§ 155.420)

We are finalizing the proposed special enrollment period at § 155.420(d)(6)(v), which will be subject to pre-enrollment verification of eligibility for the FFEs. Where possible, the FFE makes every effort to verify an individual's eligibility for the applicable special enrollment period through automated electronic means instead of through an applicant's submission of documentation. Consistent with other special enrollment periods subject to pre-enrollment verification, individuals will be required to provide supporting documentation [195] within 30 days of plan selection.

We estimate an additional 4,700 consumers will submit documents annually to verify their eligibility to enroll through the proposed special enrollment period in the FFE, and that a consumer will, on average, spend approximately 1 hour gathering and submitting required documentation. Using the average hourly wage for all occupations (at an hourly rate of $48.68), we estimate the opportunity cost to a consumer completing this task to be approximately $48.68. We estimate the total annual burden on those consumers submitting documentation will be approximately 4,700 hours with an equivalent cost of approximately $228,796.

We are revising the information collection currently approved under OMB control number 0938–1207 (CMS–10468—Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment) to account for this additional burden. SBEs that choose to operationalize the proposed special enrollment period are encouraged to follow the same approach for pre-enrollment verification of special enrollment period eligibility.

F. ICRs Regarding Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(e) will create additional costs on, or burdens to, the Exchanges. We anticipate it will decrease burden on those consumers who, when applying for a hardship exemption, choose to apply for the exemption through the IRS for 2018, saving them approximately 16 minutes since they will not be required to complete the exemption application or submit supporting documentation. HHS will continue to process exemptions under current regulations for all SBEs that elect this option, and anticipates a decrease in the volume of exemptions processed.

Based on historical data of the exemptions program and anticipating a decrease in individuals applying for exemptions as a result of the Tax Cuts and Jobs Act that reduced to $0 the individual shared responsibility payment for months beginning after December 31, 2018, we estimate that approximately 50,000 individuals will apply for a hardship exemption annually through the FFE.[196] We expect 60 percent of those individuals will apply for a hardship exemption through the IRS for 2018, totaling 30,000 requests.

We estimate that the annual reduction in burden for the expected 30,000 hardship exemptions through the IRS for 2018 will be approximately 8,100 hours. Using the average hourly wage for all occupations (at an hourly rate of $48.68 per hour) we estimate that the annual reduction in cost for each consumer will be approximately $13, and the annual cost reduction for all consumers applying for hardship exemptions through the IRS for 2018 will be approximately $394,308.

We anticipate the burden will also be reduced for those consumers who currently apply through Connecticut.[197] Based on the population of Connecticut, we expect 330 consumers from that state will apply for a hardship exemption through the IRS for 2018, as opposed to through the state Exchange. We estimate that the annual reduction in burden for the 330 hardship exemptions through the IRS will be approximately 89 hours. Using the average hourly wage for all occupations (at an hourly rate of $48.68 per hour) we estimate the annual reduction in cost for each consumer will be approximately $13, and the annual cost reduction for all consumers in Connecticut applying for a hardship

[195] Consumer submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are available at *https://www.healthcare.gov/help/prove-coverage-loss/* and *https://www.healthcare.gov/verify-information/documents-and-deadlines/*, respectively.

[196] Although the Tax Cuts and Jobs Act reduces to $0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may still have a need to seek a hardship exemption for 2019 and future years due to a lack of affordable coverage based on projected income.

[197] HHS processes exemptions for all SBEs except Connecticut.

exemption through the IRS for 2018 will be approximately $4,337.

We will revise the information collection currently approved under OMB control number 0938–1190 (CMS–10466—Patient Protection and Affordable Care Act: Exchange Functions Eligibility for Exemptions) to account for this burden reduction.

G. Summary of Annual Burden Estimates for Requirements

TABLE 11—NEW ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
155.420(d)(6)(v)	0938–1207	4,700	4,700	1	4,700	$48.68	$228,796
Total	.....	4,700	4,700	.....	4,700	.....	$228,796

* There are no capital/maintenance costs associated with the information collection requirements contained in this final rule; therefore, we have removed the associated column from Table 11.

H. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit CMS' website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule and identify the final rule (CMS–9926–F), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due May 28, 2019.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule finalizes standards related to the risk adjustment program for the 2020 benefit year, clarifications and improvements to the risk adjustment data validation program, as well as certain modifications that will promote transparency, innovation in the private sector, reduce burden on stakeholders, and improve program integrity. The Premium Stabilization Rule, previous Payment Notices, and final risk adjustment [198] rules provided details on the implementation of the risk adjustment program, including the specific parameters applicable for the 2014, 2015, 2016, 2017, 2018, and 2019 benefit years. This final rule finalizes additional standards related to cost-sharing parameters; the Exchanges, including exemptions, eligibility and enrollment; calculation of the premium adjustment percentage; and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts of this final 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 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

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 RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this final rule is likely to have economic impacts of $100 million or more in at least 1 year, and therefore, meets the definition of ''significant rule'' under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this final rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this final rule aim to ensure taxpayer money is more appropriately spent and that states have additional flexibility and control over their insurance markets. They will reduce regulatory burden, and reduce administrative costs for consumers and direct enrollment entities.

HHS anticipates that the provisions of this final rule will help further the HHS' goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed

[198] Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (Dec. 10, 2018).

choices, that the insurance market offers choices, and that states have more control and flexibility over the operation and establishment of Exchanges. Affected entities such as direct enrollment entities, and QHP issuers will incur costs to comply with the proposed new provisions, for example, those related to direct enrollment; and states will incur costs if they choose to implement the new special enrollment period. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 12 depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 12 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annualized monetized costs described in Table 12 reflect direct administrative costs and savings to health insurance issuers and consumers as a result of the provisions regarding special enrollment periods, use of direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers, and applying for hardship exemptions. The annualized monetized transfers described in Table 12 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers, the potential increase in PTC for those qualifying individuals that use the new special enrollment period, and the potential decrease in PTC and increase in health insurance provider fees and employer shared responsibility payments due to the change in the premium adjustment percentage, and the corresponding changes the Department of the Treasury and the IRS are expected to make with regard to their policies on calculating these parameters. We are finalizing the risk adjustment user fee of $2.16 per billable member per year for the 2020 benefit year to operate the risk adjustment program on behalf of states,[199] which we estimate to cost approximately $50 million in benefit year 2020. We expect risk adjustment user fee transfers from issuers to the federal government to increase by $10 million, compared to the $40 million estimated for the 2019 benefit year; this increase is included in Table 12. Additionally, we are finalizing an FFE user fee rate of 3.0 percent of premiums for the 2020 benefit year, which is lower than the 3.5 percent FFE user fee rate finalized for 2014 to 2019 benefit years. We are also finalizing an SBE–FP user fee rate of 2.5 percent of premiums for the 2020 benefit year, which is lower than the 3.0 percent SBE–FP user fee rate we finalized for the 2019 benefit year. Also, we are updating the premium adjustment percentage for the 2020 benefit year, resulting in a final premium adjustment percentage of 1.2895211380 percent.

TABLE 12—ACCOUNTING TABLE

Benefits:

Qualitative:

- Greater market stability resulting from updates to the risk adjustment methodology.
- Potential increased enrollment in the individual market stemming from lower premiums due to expansion of direct enrollment opportunities, leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- Greater continuity of coverage for consumers related to the special enrollment period.
- Reduced Navigator training compliance burden and increased flexibility in training design for Exchanges by streamlining the existing training topics into four broad categories.
- Reduced burden to FFE Navigators by making the duties listed at § 155.210(e)(9) permissible for FFE Navigators, not required.
- Strengthened program integrity related to agents and brokers and direct enrollment entities.
- Reduction in burden associated with risk adjustment data validation for issuers eligible for the liquidation exemption.
- Potential reduction in economic distortions, and improvement in economic efficiency as a result of the reduction in Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	−$14.042	2018	7	2019–2023
	−$14.037	2018	3	2019–2023

Quantitative:

- Costs incurred by issuers and consumers to comply with provisions related to special enrollment periods.
- Reduction in burden and costs for consumers applying for hardship exemptions through IRS.
- Reduction in burden and cost for direct enrollment entities that choose to use direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers.
- Regulatory familiarization costs.

Qualitative:

- Costs to issuers due to increases in providing medical services if health insurance enrollment increases.
- Potential costs to Exchanges that opt to implement the special enrollment period for qualified individuals who experience a decrease in household income and are newly determined eligible for APTC, and to issuers for processing related enrollments and terminations.

[199] As noted earlier in this final rule, no state has elected to operate the risk adjustment program for the 2020 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia.

TABLE 12—ACCOUNTING TABLE—Continued

Transfers:	Estimate (million)	Year Dollar	Discount Rate (percent)	Period Covered
Federal Annualized Monetized ($/year)	$954	2018	7	2019–2023
	$976.6	2018	3	2019–2023

Quantitative:

- Transfer from health insurance issuers to the federal government of $50 million as risk adjustment user fees for 2023 (the amount will increase by $10 million from that previously estimated for 2020–2022).
- Transfer from federal government of $15.3 million in premium tax credits to consumers enrolling through special enrollment period.
- Health Insurance Providers Fees of approximately $50 million in 2020 and $70 million per year between 2021 and 2023, which is a transfer from issuers to the federal government, and Employer Shared Responsibility Payments of $100 million in 2020 and $110 million per year between 2021 and 2023, which is a transfer from employers to the federal government.
- Reductions in federal premium tax credit spending of approximately $980 million in 2020, $1.04 billion in 2021, $1.09 billion in 2022 and $1.15 billion in 2023, which is a transfer from consumers to the federal government, due to the change in the method of calculating the premium adjustment percentage.
- Between 2020 and 2023, net premium increases of approximately 1 percent or $181 million in additional net premiums per year, which is a transfer from consumers and the federal government to issuers.

Qualitative:

- The net effect on premiums is uncertain.
- Potential increase in federal and state uncompensated care costs as a result of lower Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the PPACA's impact on federal spending, revenue collection, and insurance enrollment. The PPACA transitional reinsurance and temporary risk corridors programs ended after the 2016 benefit year. Therefore, the costs associated with those programs are not included in Tables 12 or 13 for fiscal years 2020–2023. Table 13 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2019 through 2023, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the risk adjustment program that is described in Table 13. We note that transfers associated with the risk adjustment program were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 12).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on this internal analysis, we anticipate that the quantitative effects of the provisions in this final rule are consistent with our previous estimates in the 2019 Payment Notice for the impacts associated with the APTC, the premium stabilization programs, and FFE user fee requirements.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT PROGRAMS FROM FISCAL YEAR 2019–2023

[In billions of dollars]

Year	2019	2020	2021	2022	2023	2019–2023
Risk Adjustment Program Payments	5	6	6	6	7	30
Risk Adjustment Program Collections*	5	6	6	7	7	31

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipts will fully offset payments over time.
Note 2: The CBO score reflects an additional $1 million in payments in FY 2018 that are collected in prior fiscal years. CBO does not expect a shortfall in these programs.
Source: Congressional Budget Office. *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028* Table 2. May 2018. Available at *https://www.cbo.gov/system/files?file=2018-06/51298-2018-05-healthinsurance.pdf.*

1. Risk Adjustment

The risk adjustment program is a permanent program created by section 1343 of the PPACA that collects charges from issuers with lower-than-average risk populations and uses those funds to make payments to issuers with higher-than-average risk populations in the individual, small group, and merged markets (as applicable), inside and outside the Exchanges. We established standards for the administration of the risk adjustment program in subparts A, B, D, G, and H of 45 CFR part 153.

A state approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. Consistent with § 153.610(f), if HHS operates risk adjustment on behalf of a state, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2020 benefit year, we estimated that the total cost for HHS to operate the risk adjustment program on behalf of all states will be approximately $50 million, and that the risk adjustment user fee will be approximately $2.16 per billable member per year, or $0.18 PMPM. The updated cost estimates attribute all costs related to the EDGE server data collection and data evaluation (quantity and quality evaluations) activities to the risk adjustment program, rather than sharing

them with the reinsurance program, which is no longer operational. Previously, we had collected amounts for reinsurance administrative expenses, which partially funded contracts that were used for both the risk adjustment and reinsurance programs. Now, those costs are borne by the risk adjustment program alone. Additionally, based on experience with the risk adjustment data validation program's development and execution, including development of the new risk adjustment data validation audit tool and additional contractor support for processing risk adjustment data validation discrepancies and appeals, we estimate higher costs associated with the risk adjustment data validation program. Finally, we are incorporating the full amount of eligible personnel and administrative costs associated with risk adjustment program development and operations, including indirect costs, in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fees in the 2019 Payment Notice final rule incorporated only a portion of the eligible personnel costs, and excluded indirect costs. Finally, we estimate similar billable member month enrollment for the 2020 benefit year as the most recent 2017 benefit year individual and small group market enrollment.

We believe that the approach of blending (or averaging) 3 years of separately solved coefficients from the 2016 and 2017 benefit year enrollee-level EDGE data with the 2015 MarketScan® data will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2019 benefit year to the 2020 benefit year due to differences in the datasets' underlying populations. Furthermore, we are finalizing the use of enrollee-level EDGE data and reports extracted from issuer EDGE servers to calibrate and operationalize HHS programs for the individual and small group (including merged) market programs, as well as to more broadly conduct policy analysis for the individual and small group (including merged) markets.

2. Risk Adjustment Data Validation (§ 153.630)

Under § 153.630, we proposed a few changes to the requirements for risk adjustment data validation.

We are finalizing the changes to the pairwise means test that will increase the second validation audit sample to the full 200 enrollee sample size (rather than 100) in certain cases. We do not believe this policy will increase the burden on issuers because the second validation audit is conducted by HHS, not issuers, and issuers are already required to provide the initial and second validation audit entities with the documentation necessary to complete the audits for all 200 enrollees sampled. Instead, we believe that increasing the second validation audit sample size to the full initial validation sample of 200 enrollees, in certain cases, may increase the costs to the federal government of conducting the second validation audit, as HHS will now review the documentation submitted for all 200 enrollees, rather than only 100 in certain cases. However, we believe that the benefits from improving the process for validating the second validation audit results and the accompanying precision it will bring to risk score error rate adjustments will outweigh the increased costs to the federal government and better ensure the integrity of the risk adjustment program.

We are finalizing our proposal to incorporate prescription drugs into risk adjustment data validation as part of the data validation process. We believe that it is important that prescription drugs are validated as part of risk adjustment data validation, as the HHS-operated risk adjustment methodology started incorporating prescription drug factors beginning with the 2018 benefit year. HHS previously estimated the burden of incorporating drugs in risk adjustment data validation in the 2018 Payment Notice.

The exemptions in this final rule for risk adjustment data validation codify two policies finalized in the 2018 and 2019 Payment Notices and also include one new exemption policy for issuers in or entering liquidation. The impact of the previously finalized exemptions was addressed in the 2018 and 2019 Payment Notices. We believe that the number of issuers that will qualify for the exemption for issuers in liquidation will be very small each year, and therefore, we believe that the overall reduction in burden will be limited. However, those issuers that are exempted from risk adjustment data validation will have less burden and administrative costs than an issuer subject to these requirements.

3. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

In § 155.220(c)(3)(i), the new paragraph (c)(3)(i)(L) prohibits web-brokers from displaying QHP recommendations on their websites based on compensation a web-broker, agent, or broker receives from QHP issuers. Web-brokers often collect certain information from consumers and on the basis of that information display or sort QHPs, or apply a score to all available QHPs, indicating which QHP they believe is the best option for those consumers. We support the development and use of innovative consumer-assistance tools that may help consumers select QHPs that best fit their needs. However, we believe such recommendations should be based on information consumers have provided to web-brokers and not based on compensation received from QHP issuers when consumers enroll in their plans. We are not aware of any web-brokers currently recommending QHPs based on compensation received from QHP issuers, so we expect the impact of this provision to be very limited.

We are finalizing the requirement in § 155.220(c)(4)(i)(A) for web-brokers to provide HHS with a list of agents or brokers who, through a contract or other arrangement, use the web-brokers' websites to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form or manner to be specified by HHS. The authority currently exists for HHS to obtain this information by request. However, due to the trend of increased use and expansion of direct enrollment pathways, we believe it is appropriate and necessary to collect this information proactively, so that we may respond more efficiently and effectively to any potential instances of noncompliance that may involve use of a web-broker's direct enrollment pathway. Having this information will, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We will release guidance that provides details on the form and manner of these submissions. We anticipate that it will require the list to include, at minimum, each agent's or broker's name, state(s) of licensure, and National Producer Number. We believe the burden associated with this data collection will be relatively limited, as we understand that web-brokers collect and store this information as part of their normal business operations to identify individual agents or brokers utilizing their systems. The burden related to this provision is discussed previously in the Collection of Information Requirements section.

Under new § 155.220(g)(3)(ii), HHS is allowed to immediately terminate an agent's or broker's agreement if the agent or broker fails to maintain

applicable state licensure as an agent, broker, or insurance producer in every state in which the agent or broker actively assists consumers with applying for APTC or CSRs or with enrolling in QHPs through the FFEs or SBE–FPs. State licensure for agents and brokers in every state in which they are assisting consumers is a fundamental consumer protection and critical for program integrity. It has been a requirement in the FFE agreements with agents and brokers since the inception of the FFEs, and is adhered to by the overwhelming majority of agents and brokers. Therefore, we believe the impact of this provision on agents and brokers will be minimal, but the proposal will benefit consumers who might otherwise interact with unlicensed individuals and will improve Exchange program integrity.

In § 155.220(k) a new paragraph (k)(3) is added that will allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction. This language is identical to an existing provision that applies to web-brokers at § 155.220(c)(3)(i)(L) and a similar provision applicable to QHP issuers participating in direct enrollment at § 156.1230(b)(1). Those provisions are being replaced with a very similar new requirement that applies to both types of direct enrollment entities in new § 155.221(d). Because the potential risks posed by agents and brokers with access to FFE systems are similar to those posed by web-brokers and QHP issuers participating in direct enrollment, we believe this change is necessary and appropriate to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We note that agents and brokers whose ability to transact information with the Exchange is suspended under this authority will remain registered and authorized to assist consumers using the Marketplace (or side-by-side) pathway, unless and until their agreements are suspended or terminated under § 155.220(f) or (g). We believe this authority will be used infrequently and only in cases where there will likely be the reasonable basis to suspend their agreements under § 155.220(g)(5)(i) but there is a need to take immediate action to protect sensitive consumer data or Exchange systems and operations. Therefore its effect on agents and brokers is expected to be relatively limited.

In § 155.220(m)(1), we are finalizing the provision to allow a web-broker's agreement to be suspended or terminated for cause under § 155.220(g), and a web-broker to be denied the right to enter into agreements with the FFEs under paragraph (k)(1)(i) of this section based on the actions of its officers, employees, contractors, or agents, even if those persons are not agents or brokers registered with the FFE. In § 155.220(m)(2), we are finalizing the provision to allow a web-broker's agreement to be suspended or terminated under § 155.220(g), and for the entity to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under the common ownership or control, or is an affiliated business, of another web-broker that has had its agreement suspended or terminated for cause. We expect these provisions to have limited impact, as they are designed to protect program integrity and will only be utilized in limited cases when there is evidence of significant misconduct or non-compliance. In those cases, we anticipate benefits to consumers stemming from our enhanced ability to address program integrity concerns and non-compliance issues. In § 155.220(m)(3), we are finalizing the requirement for the Exchange to collect information from a web-broker sufficient to establish the identities of individuals who comprise its corporate leadership and to determine any business relationships with other entities that may seek to register with the Exchange as web-brokers. These provisions are also intended to protect program integrity by enabling the Exchange to have information necessary to determine if any individuals seeking to be web-brokers are attempting to circumvent a previous termination or suspension for cause of FFE agreements. The burden related to this provision is discussed in the Collection of Information Requirements section.

4. Direct Enrollment (§§ 155.20, 155.220, 155.221, 155.415, 156.1230)

The changes to § 155.220 are discussed above. In § 155.221, we amend and redesignate the existing paragraphs (a), (b) and (c) to new paragraphs (e), (f), and (g). In new § 155.220(e), we add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with new § 155.221(b)(4) [200] be independent of the entities they are auditing. We believe an independent audit is less likely to be influenced by a direct enrollment entity's business considerations, and therefore, is more reliable. We expect no impact from this provision as it was included as a requirement in the agreements we executed with direct enrollment entities subject to these audits for plan year 2019. We also clarify in § 155.221(e) that an initial audit is required, in addition to subsequent annual audits. This clarification does not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections.[201] Therefore we anticipate no impact of this proposed change. In § 155.221(f), we require that a written agreement must be executed between a direct enrollment entity and its auditor stating that the auditor will comply with the requirements of paragraph (f). We believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement. We expect most, if not all, direct enrollment entities already execute written agreements with their contractors that will incorporate any regulatory requirements that fall within the scope of the work the contractor is performing for the entity, so we expect little to no impact from this change.

In the new § 155.221(a), we are codifying in regulation the types of entities the FFEs permit to offer non-Exchange websites to facilitate direct enrollment in coverage offered through the Exchange in a manner that is considered to be through the Exchange. There are two types of entities that are authorized by the FFEs to offer direct enrollment pathways: QHP issuers and web-brokers. We expect this provision to have little or no impact as QHP issuers and web-brokers are already authorized by the FFEs to participate in direct enrollment.

In the new § 155.221(b), we establish and consolidate certain requirements that apply to all direct enrollment entities. Specifically, we add in § 155.221(b)(1) that QHPs and non-

[200] Direct enrollment operational readiness review requirements are currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers.

[201] See § 156.1230(b)(2) for issuers participating in direct enrollment and § 155.220(c)(3)(i)(K) for web-brokers.

QHPs must be displayed and marketed on separate website pages on the direct enrollment entity's non-Exchange website. We consider this a clarification of existing standards that will have minimal impact on direct enrollment entities, and will minimize the chance that consumers are confused by the display or marketing of QHPs and non-QHPs on a single website page. In the new § 155.221(b)(2) we require the prominent display of a standardized disclaimer in a form and manner provided by HHS. Similar uniform disclaimer requirements already exist for all direct enrollment entities. As a result, and because we will provide the disclaimer text, we expect the overall impact of this provision to be minimal. In the new § 155.221(b)(3), we limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process on direct enrollment entities' websites in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. This will also assist consumers in understanding the applicability of APTC and CSRs that they may be eligible for. Most direct enrollment entities have refrained from marketing non-QHPs in conjunction with QHPs citing a lack of clear guidance on what was permissible. Therefore we expect the impact of this provision to be minimal, and to be perceived as allowing increased flexibility. In the new § 155.221(b)(4), we consolidate a provision requiring direct enrollment entities demonstrate operational readiness and compliance with applicable requirements prior to the entities' websites being used to complete an Exchange eligibility application or a QHP selection. Because this is an existing requirement, we expect no impact.

In the new § 155.221(c), the authority to use application assisters and the corresponding requirements when doing so apply for all issuers and direct enrollment entities and not solely QHP issuers. We are finalizing a new definition of ''direct enrollment entity application assister'' in § 155.20 that mirrors the existing definition of ''issuer application assister'', as well as finalizing amendments to § 155.415 to capture the requirements for entities using application assisters that align with the existing requirements currently in § 156.1230(a)(2) for QHP issuer application assisters. There is one significant deviation from the existing requirements for application assisters. Currently, § 156.1230(a)(2)(i) requires all application assisters to receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. Licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs or SBE–FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assisters to have similar access to FFE systems, so that they are also able to assist consumers as described here and in the preamble in this rule, they will need credentials similar to those obtained by agents and brokers during FFE registration and training. Therefore, we require that application assisters providing assistance in the FFEs and SBE–FPs comply with this training requirement by completing a similar registration and training process, in a form and manner to be specified by HHS, so that they will have the necessary credentials to provide consumer assistance. This new training and registration requirement for application assisters is captured in the new § 155.415(b)(1). The burden placed on application assisters to complete the FFE training may exceed what may have otherwise existed if direct enrollment entities were developing and managing their own training programs. However, by requiring the FFE training to be completed by application assisters assisting consumers in the FFEs and SBE–FPs, it will relieve direct enrollment entities from the burdens associated with having to develop and manage their own training programs. Importantly, FFE systems will require this approach to comply with system security requirements and to enable application assisters to meaningfully be able to assist consumers in the FFEs and SBE–FPs. Therefore, taken together, we believe the net burden associated with this requirement will be minimal and will be acceptable to participating direct enrollment entities that elect to use application assisters, when permitted under state law. The reason we believe the net burden will be minimal is because the bulk of time associated with application assisters completing the training requirement will likely be comparable whether the training is developed and administered by direct enrollment entities or by HHS. However, there will likely be a small increase in the amount of time application assisters will have to devote to the registration process apart from training, specifically to creating an FFE account and completing identity proofing. In contrast, there will likely be a substantial reduction in burden on direct enrollment entities, because they will not have to develop and manage their own training programs. Instead they will be able to simply confirm their application assisters have completed the FFE registration and training process.

We anticipate that allowing QHP issuers to use application assisters in the FFEs and SBE–FPs, and expanding that option to other issuers and web-brokers will provide cost savings to these entities. It is difficult to precisely estimate the number of applications for which a direct enrollment entity application assister provided help may be submitted. However, based on available data, we estimate that approximately 980,000 agent or broker-assisted direct enrollment applications will be submitted in plan year 2019. We estimate that it will take an insurance sales agent [202] (at an hourly rate of $64.42) one hour to complete an application. We do not have information related to the number of states that will allow for unlicensed application assisters, as well as how many direct enrollment entities will hire application assisters or train existing staff as application assisters. Therefore, we estimate that half of assisted direct enrollment applications will be completed with the assistance of an application assister instead of an agent or broker. Based on these assumptions, we estimate that it will take an insurance claims and policy processing clerk [203] (at an hourly rate of $39.52) one hour to complete each application. Thus, we estimate that the applications for 490,000 applicants will result in an estimated total burden of approximately 490,000 hours with an associated cost of approximately $19,364,800. If the applications are completed by an agent or broker instead, the total cost will be approximately $31,565,800. Based on these assumptions, we estimate an overall annual savings of approximately $12.2 million for direct enrollment entities using application assisters instead of only agents or brokers. In addition, we expect that the time that agents or brokers may otherwise have spent assisting consumers with their eligibility applications will often instead be devoted to assisting more consumers with plan selection and finalizing their enrollments. As a result, we expect this policy may also result in an overall increase in enrollment

[202] Bureau of Labor Statistics mean hourly wage for an Insurance Sales Agent (Occupational Code 41–3021) at $32.21 an hour, plus 100 percent fringe.

[203] Bureau of Labor Statistics mean hourly wage for an Insurance Claims and Policy Processing Clerk (Occupational Code 43–9041) at $19.76 an hour, plus 100 percent fringe.

through the FFEs and SBE–FPs. Lastly, these provisions provide increased flexibility and a level playing field to all direct enrollment entities and issuers.

In the new § 155.221(d), we consolidate existing authority to immediately suspend a direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the Exchange's ability to make accurate eligibility determinations, or Exchange operations or systems until such circumstances are remedied or sufficiently mitigated to HHS' satisfaction. We expect little or no impact from this proposal, since this is largely based on an existing authority.

We also codify new definitions for the following terms in § 155.20: ''direct enrollment entity'', ''direct enrollment technology provider'', and ''web-broker''. We define ''direct enrollment entity'' as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We expect no impact from this provision as it merely codifies a definition for the term in such a way that the entities that are currently authorized by the FFE to host a direct enrollment environment are direct enrollment entities. We also amend § 155.20 to define ''direct enrollment technology provider'' as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker, to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. There may be instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity engages the services of or creates a technology company that is not licensed as an agent or broker to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. In such cases, when the technology company is not itself licensed as an insurance agency or brokerage, these technology companies will be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless noted otherwise. We expect no new burden associated with this requirement as it merely allows some flexibility in terms of how licensed agents or brokers may organize their businesses or pursue business relationships when seeking to become web-brokers. We also codify a definition of ''web-broker'' as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. As explained in the preamble, we also define the term ''web-broker'' to generally include direct enrollment technology providers. Importantly, this definition will replace HHS' current web-broker definition, which is slightly different. However, we expect no impact, because all existing web-brokers will fall within the new proposed definition of web-broker.

Conforming edits were also made to § 156.1230 as part of the effort to streamline and consolidate similar requirements that apply to all direct enrollment entities in one regulation. We amend § 156.1230(b) to add a new paragraph (b)(1) that requires issuers participating in direct enrollment to comply with the applicable requirements in § 155.221. There were minimal substantive changes to the underlying requirements applicable to issuers participating in direct enrollment. We therefore expect no new impact to issuers except to the extent previously discussed. We also delete and reserve § 156.1230(a)(2) to align with the changes, described in this rule, to § 155.415 regarding application assisters.

5. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Since implementing the direct-to-issuer enrollment system in plan year 2018, we have seen a marked decrease (greater than fifty percent) in the volume of SHOP Call Center calls. We anticipate that the SHOP Call Center volume will continue to decrease in plan year 2020, as employers will be in the third year of enrolling in SHOP directly with issuers, often with the assistance of agents and brokers. In addition, agents and brokers and small employers can now resolve most issues directly with impacted issuers using well-established issuer call centers and small group processes unique to each market. We anticipate a minimal number of new appeals of SHOP eligibility and special enrollment periods given anticipated employer participation and our observation that very few employers ever appeal SHOP determinations.

In short, we will maintain a toll-free telephone hotline that the statute requires (at present 12 full-time equivalent employees are devoted to SHOP Call Center operations). We envision minimal contractor and staff support to maintain the hotline content and to respond to very few voicemail messages. Although we will maintain language translation service and incur the associated costs, we anticipate that such costs will be minimal given call volume. Moving to an interactive voice response system will eliminate staffing for 12 full-time equivalent employees required at the call center under the SHOP Plan Aggregate and Call Center contract and will provide a net savings to the government of approximately $2 million annually.

6. Navigator Program Standards (§§ 155.210 and 155.215)

We provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, not required. The amendment of § 155.210 to remove the requirement that Navigators in FFEs provide the assistance specified at § 155.210(e)(9) will reduce regulatory burden and allow FFE Navigators to better prioritize work according to consumer demand, community needs, and organizational resources. Under the provision, Navigators in FFEs may continue to provide the types of assistance listed at § 155.210(e)(9), but will not be required to do so.

The time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies. To help quantify this burden reduction, we requested comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities in § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also requested comment on how Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9). In particular, we sought comment on what tasks Navigators might prioritize and complete during the time they otherwise might have provided these types of assistance.

Commenters stated that the amount of time Navigators reported that they spent providing post-enrollment assistance varied widely. One commenter stated

that a broad range of post-enrollment activities were among the most common areas of assistance requested by consumers. Another commented that while they did not spend much time on tax processes, forms, appeals, or exemptions, the time they spent educating consumers about basic health concepts and how to use their health coverage was extensive. Another commented that, on average, Navigators visited each enrolled consumer ten times, and that three of those visits were dedicated to providing post-enrollment assistance. Another commenter stated that one of their Navigators spent 6 months and more than 40 hours helping a consumer file an appeal.

We amend Navigator training requirements at §§ 155.210(b)(2) and 155.215(b)(2) to provide greater flexibility to Exchanges in designing their Navigator training programs to ensure coverage of the most instructive and timely topics in a streamlined fashion and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their activities as required by the Navigator statute and regulations. This additional flexibility will allow Exchanges to focus on training areas they determine to be most relevant to the populations in the Exchange service area, while still addressing all required or authorized Navigator functions. Because it will provide greater flexibility to tailor the training to current, local conditions in each Exchange, the revised approach might also help to ensure cost-effective use of Exchange Navigator funding.

Moreover, we believe these changes will also grant greater flexibility to SBEs, including SBE–FPs, in designing their respective Navigator training, since SBEs that decide to authorize or require their Navigators to provide the assistance specified under § 155.210(e)(9) will not have corresponding training topics prescribed, but will have the flexibility to decide how best to prepare their Navigators to provide such assistance. This is similar to the flexibility SBEs have for creating training for other required Navigator duties. We believe granting SBEs the flexibility to focus on the topics they find best suited to prepare their Navigators for assisting consumers will allow for a more effective training program, and will reduce the regulatory compliance burden on these Exchanges.

However, the burden reduction that this will achieve cannot be estimated since these changes are not intended to reduce the total number of hours of Navigator training annually and we are uncertain how each Exchange will choose to structure its respective Navigator training given this increase in flexibility. We continue to believe that each Exchange is in the best position to determine the training that is most appropriate for the activities of its Navigators.

7. Special Enrollment Periods (§ 155.420)

We anticipate that amended § 155.420 will impose moderate costs on Exchanges that opt to implement the proposed special enrollment period to update their user interfaces and make changes to their eligibility systems, but also acknowledge that Exchanges may choose to offer the special enrollment period through their call center or other existing enrollment avenues that could greatly reduce implementation costs to an Exchange. Additionally, we anticipate that verification requirements will impose costs relating to special enrollment period pre-enrollment verification systems, caseloads, and consumer messaging for Exchanges that perform pre-enrollment verification of special enrollment period eligibility. We expect utilization of the special enrollment period may vary among Exchanges depending on total Exchange enrollment and Exchange plan rates and pricing practices. Given these variable factors, we requested comments regarding anticipated costs, benefits and implementation approaches among Exchanges to assist in forming a future estimate.

We do not anticipate this provision to significantly increase regulatory burden on issuers, but acknowledge issuers may encounter marginal costs associated with processing new enrollments and terminations related to the special enrollment period, and direct enrollment entities may also face minor implementation costs associated with updating their applications and systems to include the new special enrollment period. We estimate that it will take a mid-level software developer [204] (at an hourly rate of $107.48) approximately 10 hours to make the required modifications to the direct enrollment entity's applications and system logic. We estimate a one-time cost burden of approximately $1,075 per direct enrollment entity. We further estimate a total one-time burden for 35 direct enrollment entities will be approximately 350 hours with an equivalent cost of approximately $37,618.

Because this policy provides improved pathways to continuous coverage for special enrollment period-eligible consumers, we anticipate that the proposal will promote continuous coverage for consumers and thereby have a positive effect on the individual market risk pool. Additionally, we anticipate that eligible consumers may experience reduced out-of-pocket costs related to health care expenses resulting from access to more affordable health plans and a new pathway to maintaining continuous health care coverage, compared to if they had to drop out of off-Exchange coverage and pay out-of-pocket for all health care expenses incurred for the remainder of the year. We estimate that approximately 4,700 new consumers will use this special enrollment period on an annual basis to enroll in Exchange coverage, and that these consumers will be enrolled for an average of 6 months of Exchange coverage during the benefit year. Using the plan year 2019 average monthly APTC amount of $544, we estimate total APTC transferred to consumers as a result of the proposed special enrollment period will be approximately $15,340,800 annually.[205]

We invited comments on the potential costs and savings to Exchanges, issuers, direct enrollment entities, and consumers associated with the proposed special enrollment period. We did not receive comments on the cost estimates contained in these proposal.

8. Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(e) will create additional costs or burdens on Exchanges, and we anticipate it will decrease burden on consumers. The addition of § 155.605(e)(5) will enable individuals to claim a general hardship exemption on their federal income tax return for 2018 without an exemption certificate number from an Exchange. This policy will allow for more flexibility and will not result in any additional costs or burdens for issuers. The reduction in burden to consumers is discussed in the Collection of Information Requirements section.

9. FFE and SBE–FP User Fees (§ 156.50)

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE or SBE–FP must remit

[204] Bureau of Labor Statistics mean hourly wage for a Software Developer, Systems Software (Occupational Code 15–1133) at $53.74 an hour, plus 100 percent fringe.

[205] ASPE ''2019 Health Plan Choice and Premiums in HealthCare.gov states.'' *https://aspe.hhs.gov/system/files/pdf/260041/2019LandscapeBrief.pdf.*

a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE or SBE–FP. In this final rule, for the 2020 benefit year, we finalize an FFE user fee rate of 3.0 percent of the monthly premium, and SBE–FP user fee rate of 2.5 percent of the monthly premium. We estimate similar FFE and SBE–FP user fee transfers as those estimated for prior benefit years, and therefore, we finalized no changes to transfers from issuers to the federal government due to the finalized lower FFE and SBE–FP user fee rates.

10. Prohibition on Discrimination (§ 156.125)

In the preamble to § 156.125, we discuss a potentially discriminatory benefit design under § 156.125: the exclusion of MAT drugs for the treatment of opioid use disorder while covering the same drugs for other medically necessary purposes, such as analgesia or alcohol use disorder. Because we did not propose a change to this policy, we do not anticipate any additional burden on states or issuers. However, to the extent this clarification causes issuers to cease prohibited discriminatory practices, the clarification could help consumers obtain needed MAT, lead to better health outcomes, and reduce the burden and out-of-pocket costs individuals may have otherwise incurred in attempts to obtain MAT.

11. Provisions Related to Cost-Sharing (§ 156.130)

We are finalizing a premium adjustment percentage of 1.2895211380 for the 2020 benefit year. The annual premium adjustment percentage is used to set the rate of increase for several parameters detailed in the PPACA, including: the annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)), and the employer shared responsibility payments under sections 4980H(a) and 4980H(b) of the Code.

Additionally, we finalized other cost-sharing parameters using an index based on the final premium adjustment percentage for the 2020 benefit year. In § 155.605(d)(2), we are finalizing a required contribution of 8.24 percent for the 2020 benefit year, which reflects the premium adjustment percentage calculation for the 2020 benefit year detailed in preamble.[206] In § 156.130(a)(2), we are finalizing a maximum annual limitation on cost sharing of $8,150 for self-only coverage, and $16,300 for other than self-only coverage. The CMS Office of the Actuary estimates that the proposed change in methodology for the calculation of the premium adjustment percentage may have the following impacts between 2019 and 2023: [207]

TABLE 14—IMPACTS OF MODIFICATIONS TO THE 2020 BENEFIT YEAR PREMIUM ADJUSTMENT PERCENTAGE

Calendar year	2019	2020	2021	2022	2023
Exchange Enrollment Impact (enrollees, thousands)	N/A	−70	−70	−70	−70
Premium Impacts:					
Gross Premium Impact (change from 2018, %)	N/A	0%	0%	0%	0%
Net Premium Impact (change from 2018, %)	N/A	1%	1%	1%	1%
Federal Impacts (dollars, millions):					
Premium Tax Credits (million, $)	N/A	−980	−1,040	−1,090	−1,150
Health Insurance Providers Fee Impact (million, $)	N/A	50	70	70	70
Employer Shared Responsibility Payment Impact (million, $)	N/A	100	110	110	110
Total Federal Impact (million, $)*		−1,130	−1,220	−1,270	−1,330

*Note: While the premium tax credit impact figures are negative to signify reductions in Federal outlays, and the Health Insurance Providers Fee and the employer shared responsibility payment figures are positive to signify increased revenue to the Federal government, they are totaled together to indicate savings for the Federal government.

As noted in Table 14, we expect that the proposed change in measure of premium growth used to calculate the premium adjustment percentage for the 2020 benefit year may result in:

- Net premium increases of approximately $181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2020 through 2023 benefit years. Net premiums are calculated for Exchange enrollees as premium charged by issuers minus APTC. Gross premiums will be virtually unchanged.
- A decrease in federal PTC spending of $980 million to $1.15 billion between 2020 and 2023, due to an increase in the PTC applicable percentage and a decline in Exchange enrollment of approximately 70,000 individuals in each benefit year, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this final rule for purposes of calculating the indexing of the PTC applicable percentage and the required contribution percentage under section 36B of the Code.
- Increased Health Insurance Providers Fees on health insurance issuers of approximately $50 million in 2020, and $70 million in years 2021 to 2023, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this final rule for purposes of calculating the indexing of the Health Insurance Providers Fee.

[206] As explained in § 155.605(d)(2), for plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. To calculate the final required contribution, we used the final premium adjustment percentage in the calculation: 8.00* 1.0296274251 (1.2895211380/1.2524152976), or 8.24 percent.

[207] CMS Office of the Actuary's estimates are based on their health reform model, which is an amalgam of various estimation approaches involving federal programs, employer-sponsored insurance, and individual insurance choice models that ensure consistent estimates of coverage and spending in considering legislative changes to current law.

• Increased Employer Shared Responsibility Payments of $100 million in 2020, and $110 million each year between 2021 and 2023.

Comment: One commenter, citing the Center on Budget and Policy Priorities, suggests the proposal would reduce premium tax credits for millions of consumers. For example, a family of four with an annual income of $90,000 would pay $220 more for their coverage (the effect would be smaller for premium tax credit recipients with lower household incomes). The commenter noted that these changes would also mean more people would be considered to have an ''affordable'' offer of employer coverage, and therefore, would be ineligible for the premium tax credit. These changes would reduce the overall affordability of coverage and the number of people covered.

Response: As stated elsewhere in this rule, while we acknowledge the impact of the decrease in premium tax credits, we believe this is a technical adjustment to reflect premium growth in the entire individual market. Moreover, the benefits due to the decrease in federal expenditures outweigh those concerns and will be ultimately beneficial to taxpayers. Furthermore, we note that the 2020 required contribution percentage is lower than the 2019 required contribution percentage under the finalized method for measuring premium growth.

Some of the 70,000 individuals estimated to not enroll in Exchange coverage each year as a result of the proposed change in the measure of premium growth used to calculate the premium adjustment percentage may purchase short-term, limited-duration insurance or join a spouse's plan, though a majority is likely to become uninsured. Either transition may result in greater exposure to health care costs, which previous research suggests reduces utilization of health care services.[208] Economic distortions may be reduced, and economic efficiency and social benefits improved, because these individuals will be bearing a larger share of the costs of their own health care consumption, potentially reducing spending on health care services that are personally only marginally valued but that imposes costs on the federal government through subsidies. In addition, to the extent that this final rule reduces federal outlays and thereby reduces the need to collect taxes in the future, the distortionary effects of taxation on the economy may be reduced. However, the increased number of uninsured may increase federal and state uncompensated care costs.

As noted in this rule, the premium adjustment percentage is the measure of premium growth that is used to set the rate of increase for the maximum annual limitation on cost sharing, defined at § 156.130(a). In § 156.130(a)(2), we proposed a maximum annual limitation on cost sharing of $8,200 for self-only coverage. We are finalizing a maximum annual limitation on cost sharing of $8,150. Additionally, we proposed and are finalizing reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analyses in previous Payment Notices, we developed three test silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2020 maximum annual limitation on cost sharing for self-only coverage. We do not believe the finalized changes to the reductions in the maximum annual limitation on cost sharing for silver plan variations will result in a significant economic impact.

12. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the final rule, we assume that the total number of unique commenters on the proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters will be a fair estimate of the number of reviewers of this final rule.

We are required to issue a substantial portion of this final rule each year under our regulations and we estimate that approximately half of the remaining provisions will cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to issue each year.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $107.38 per hour, including overhead and fringe benefits.[209] We received 26,129 comments on the proposed rule, of which 497 comments were unique and 25,632 comments were substantially similar to one of eight different letters. We assume that for form letters, only the staff at the organization that arranged for those letters will review the final rule. Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review the relevant portions of this final rule that causes unanticipated burden. We assume that 497 entities will review this final rule. For each entity that reviews the rule, the estimated a cost of approximately $107.38. Therefore, we estimate that the total cost of reviewing this regulation is approximately $53,368 ($107.38 × 497 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. In this rule, we discuss the key regulatory alternatives to the finalized provisions that we considered.

In proposing the risk adjustment model recalibration in part 153, we considered multiple alternatives such as maintaining the prior year's recalibration methodology of recalibrating the models using 2 years of MarketScan® data and the most recent year of EDGE data. We also considered recalibrating the models using the most recent year of MarketScan® data available (2017) and the 2 most recent years of enrollee-level EDGE data (2016 and 2017). However, we are finalizing recalibration of the models using 3 years of blended data from the following sources: the 2 most recent years of enrollee-level EDGE data (2016 and 2017) available and 2015 MarketScan® data.

Regarding proposed changes to §§ 155.210 and 155.215, we considered taking no action to amend certain Navigator training requirements and duties, but determined that the proposed changes regarding training requirements will provide Exchanges

[208] Manning, W.G., Newhouse, J.P., Duan, N., Keeler, E.B., & Leibowitz, A. (1987). Health insurance and the demand for medical care: evidence from a randomized experiment. The American economic review, 251–277; Keeler, E.B., & Rolph, J.E. (1988). The demand for episodes of treatment in the health insurance experiment. Journal of health economics, 7(4), 337–367; Finkelstein, A., et al. (2012). The Oregon health insurance experiment: evidence from the first year. The Quarterly journal of economics, 127(3), 1057–1106.

[209] *https://www.bls.gov/oes/current/oes_nat.htm.*

with needed flexibility, and the proposed changes regarding duties of FFE Navigators will help reduce burden on FFE Navigators.

In proposing revisions to § 155.221, we considered maintaining the existing regulatory framework that established standards for issuers and web-brokers participating in direct enrollment in separate sections, but we believe streamlining and consolidating the requirements applicable to all direct enrollment entities, when possible, improves clarity and promotes fair competition. For the display requirements at § 155.221(b), we contemplated maintaining the current standards in regulations and guidance, but based on feedback received from direct enrollment entities, we believe the current framework may have caused confusion and limited innovation. Therefore, we determined that the establishment of clarified standards for the marketing and display of QHPs and non-QHPs is the best way to provide greater clarity for direct enrollment entities about what is required to minimize the potential for consumer confusion, while allowing direct enrollment entities more flexibility to be innovative in the marketing of non-QHPs to consumers who are interested in those products. For the addition of a new § 155.221(c), we considered continuing to limit the authority to use application assisters to QHP issuers. However, to promote fair competition for all direct enrollment entities and issuers, we believe a better approach is to expand this authority to include all direct enrollment entities and all issuers.

In proposing revisions to § 155.420 governing Exchange special enrollment periods, we considered broader eligibility requirements for the special enrollment period proposed at § 155.420(d)(6)(v). We considered if a special enrollment period could be offered without a decrease in household income to all Exchange applicants who were enrolled in MEC and determined eligible for APTC by the Exchange, or if changes in the applicant's household size could be considered in the eligibility criteria for this special enrollment period. We determined that eliminating the criteria for a decrease in household income will be problematic because it eliminates a triggering event for the special enrollment period and could allow for consumers who are potentially APTC-eligible to avoid the metal level restrictions in paragraph (a)(4) of this section by initially enrolling in off-Exchange coverage and then later choosing to buy a higher or lower level of coverage mid-year. We also determined that verification of household size changes will be operationally problematic, as electronic data sources will not reflect recent changes to household size. Further, the special enrollment periods at § 155.420(d)(2)(i) are currently available to qualified individuals whose household size changes due to gaining or becoming a dependent and already provides a pathway to Exchange coverage for individuals in this situation.

We also considered if the special enrollment period proposed at § 155.420(d)(6)(v) could be offered without a prior coverage requirement and determined that this requirement is necessary to ensure the special enrollment period is only available to the intended population, to promote continuous coverage among individual market enrollees, and to protect the individual market risk pools against adverse selection. Finally we considered the impact of not proposing this special enrollment period. Without the proposed special enrollment period at § 155.420(d)(6)(v), unsubsidized off-Exchange consumers who experience a decrease in household income midyear and are determined APTC eligible will remain without a pathway to Exchange coverage. These consumers will remain at risk of terminating their unsubsidized coverage midyear because it is unaffordable, rather than maintaining continuous enrollment in health coverage by transitioning to an Exchange plan.

Regarding the proposed change to § 155.605(e) to allow consumers to claim all general hardship exemptions through the federal tax filing process for the 2018 tax year, we considered that without the recommended revisions to § 155.605(e), individuals may experience a general hardship that prevents them from obtaining qualifying health coverage, and may experience undue burden to apply and qualify for an exemption from the individual shared responsibility provision. This change allows for more flexibility for individuals to claim these exemptions through the IRS tax filing process for the 2018 tax year.

We are finalizing our proposed change to the premium measure used in the premium adjustment percentage calculation under § 156.130 to use a private health insurance premium measure (excluding Medigap and property and casualty insurance) in addition to employer sponsored health insurance premiums. However, we considered other alternatives to the final premium measure and methodology for calculating the premium adjustment percentage for the 2020 benefit year. We considered finalizing our proposed method with a gradual phase-in. We also considered maintaining our previous process of using employer-sponsored insurance premium amounts. In addition, we considered using NHEA estimates and projections of private health insurance premium measure, which includes premiums for employer-sponsored insurance, direct purchase insurance (which includes Medigap insurance), and property and casualty insurance. However, we ultimately decided not to propose or finalize the use of a private health insurance measure that included Medigap insurance because we believed it was inappropriate to include Medigap premiums in the measure as this type of coverage is not considered primary coverage for those enrollees who supplement their Medicare coverage with these plans. Moreover, although total spending for private health insurance in the NHEAs includes the medical portion of accident insurance (property and casualty insurance), we did not believe it would be appropriate to include those expenditures for this purpose as they are associated with policies that do not serve as a primary source of health insurance coverage. For the reasons explained in more detail in the preamble for § 156.130, we ultimately decided to finalize the proposal as proposed.

At § 156.130 we also proposed that plans not be required to count drug manufacturer coupons toward the annual limitation on cost sharing, starting with plan years beginning on or after January 1, 2020. We considered not proposing this flexibility, as these coupons may result in lower costs to individual consumers. However, manufacturer coupons may incentivize selection of higher-cost drugs when a less costly therapeutic equivalent is available which can distort the market and the true costs of drugs, adding significant long-term costs to the health care system.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small

government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, the standards for the risk adjustment and risk adjustment data validation programs are intended to stabilize premiums. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.[210] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report [211] submissions for the 2016 MLR reporting year, approximately 85 out of over 520 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 79 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $38.5 million.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not affect small rural hospitals. Therefore, the Secretary has determined that this will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that includes any federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis.

While developing this final rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is our view that we have complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, or risk adjustment program, much of the initial cost of creating these programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has Federalism implications because it finalizes a change to the Alabama risk adjustment program in the small group market based upon a proposal provided by the state. We also proposed to make the special enrollment period at § 155.420(d)(6)(v) at the option of Exchanges, to give states flexibility in whether they choose to implement it.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller for review.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This final rule is an E.O. 13771 deregulatory action.[212]

J. Conclusion

The analysis in this rule, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation

[210] *https://www.sba.gov/document/support—table-size-standards.*

[211] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[212] We estimate cost savings of approximately $14.3 million in 2019 and annual cost saving of approximately $14 million thereafter. Thus the annualized value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is $8.51 million.

was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR as set forth below.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300-gg–92.

■ 2. Section 146.152 is amended by revising paragraph (a) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (f) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

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

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92 as amended.

■ 4. Section 147.106 is amended by revising paragraph (a) to read as follows:

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (e) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 5. The authority citation for part 148 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300–gg92, as amended.

■ 6. Section 148.122 is amended by revising paragraph (b)(1) to read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (c) through (g) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 7. The authority citation for part 153 is revised to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 8. Section 153.20 is amended by revising the definition of ''Risk adjustment covered plan'' to read as follows:

§ 153.20 Definitions.

* * * * *

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(b) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

* * * * *

■ 9. Section 153.320 is amended by revising paragraph (d) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) *State flexibility to request reductions to transfers.* Beginning with the 2020 benefit year, States can request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged markets risk pools by up to 50 percent in States where HHS operates the risk adjustment program.

(1) *State requests.* State requests for a reduction to transfers must include:

(i) Supporting evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State market risk pool;

(ii) The adjustment percentage of up to 50 percent requested for the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool; and

(iii) A justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account

for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(2) *Timeframe to submit reduction requests.* States must submit requests for a reduction to transfers in the individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by August 1 of the benefit year that is 2 calendar years prior to the applicable benefit year, in the form and manner specified by HHS.

(3) *Publication of reduction requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters rule and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

(4) *HHS approval.* (i) Subject to paragraph (d)(4)(ii) of this section, HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and relevant public comments:

(A) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or

(B) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(ii) HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction amount. HHS will assess other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool.

■ 10. Section 153.630 is amended by—

■ a. Revising paragraphs (b)(10) and (d)(2); and

■ b. Adding paragraph (g)

The revisions and addition read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(10) If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default data validation charge.

* * * * *

(d) * * *

(2) Within 30 calendar days of the notification by HHS of the findings of a second validation audit (if applicable) or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.

* * * * *

(g) *Exemptions.* An issuer of a risk adjustment covered plan will be exempted by HHS from the data validation requirement set forth in paragraph (b) of this section for a given benefit year if:

(1) The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a Statewide basis;

(2) The issuer is at or below the materiality threshold as defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits); or

(3) The issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that:

(i) The issuer provides to HHS, in the manner and timeframe specified by HHS, an attestation that the issuer is in liquidation or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer; and

(ii) The issuer is not a positive error rate outlier under the error estimation methodology in risk adjustment data validation for the prior benefit year of risk adjustment data validation.

(iii) For purposes of this paragraph (g)(3), liquidation means that a State court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 11. The authority citation for part 155 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 12. Section 155.20 is amended by adding definitions of ''Direct enrollment entity,'' ''Direct enrollment entity application assister,'' ''Direct enrollment technology provider,'' and ''Web-broker'' to read as follows:

§ 155.20 Definitions.

* * * * *

Direct enrollment entity means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by § 155.220(c)(3), § 155.221, or § 156.1230 of this subchapter.

Direct enrollment entity application assister means an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under State law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs.

Direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent, broker, or producer under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate

participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* * * * *

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in qualified health plans offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. The term also includes a direct enrollment technology provider.

■ 13. Section 155.205 is amended by revising paragraph (a) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (2)(i), and (3) of this section, unless it is an Exchange described in paragraphs (a)(1) or (2) of this section, in which case, the Exchange must provide at a minimum a toll-free telephone hotline that includes the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

(1) An Exchange described in this paragraph is one that enters into a Federal platform agreement through which it relies on HHS to operate its eligibility and enrollment functions, as applicable.

(2) An Exchange described in this paragraph is a SHOP that does not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, but rather provides for enrollment through SHOP issuers or agents and brokers registered with the Exchange.

* * * * *

■ 14. Section 155.210 is amended by—
■ a. Revising paragraphs (b)(2) introductory text, (b)(2)(iii), and (iv);
■ b. Removing paragraphs (b)(2)(v) through (ix); and
■ c. Revising paragraph (e)(9) introductory text.

The revisions read as follows:

§ 155.210 Navigator program standards.

* * * * *

(b) * * *

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure the entities and individuals are qualified to engage in Navigator activities, including training standards on the following topics:

* * * * *

(iii) The range of QHP options and insurance affordability programs; and

(iv) The privacy and security standards applicable under § 155.260.

* * * * *

(e) * * *

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In Federally-facilitated Exchanges, Navigators are required to provide information and assistance with all of the following topics under Navigator grants awarded in 2018, and will be authorized to provide information and assistance with all of the following topics under Navigator grants awarded in 2019 or any later year.

* * * * *

■ 15. Section 155.215 is amended by revising paragraph (b)(2) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(b) * * *

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§ 155.205(d) and (e) and 155.210 must receive training consistent with standards established by the Exchange consistent with § 155.210(b)(2).

* * * * *

■ 16. Section 155.220 is amended by—
■ a. Revising the section heading;
■ b. Revising paragraphs (a) introductory text, (c) introductory text, (c)(1), (c)(3)(i) introductory text and (c)(3)(i)(A), (c)(3)(i)(K) and (L), (c)(3)(ii) introductory text, (c)(4) introductory text, (c)(4)(i) introductory text, (c)(4)(i)(A), (c)(4)(i)(E), (c)(4)(i)(F), (c)(4)(ii), (c)(5), (d) introductory text, (d)(2), (e), (f)(1), (f)(2), (f)(3) introductory text, (f)(3)(i), (f)(4), (g)(1), (g)(2) introductory text, (g)(2)(iii), (g)(2)(iv), (g)(3), (g)(4), (g)(5)(i), (g)(5)(ii), (g)(5)(iii), (h)(1), (h)(2), (h)(3), (i), (j)(1) introductory text, (j)(3), (k)(1) introductory text, (k)(2);
■ c. Adding paragraph (k)(3);
■ d. Revising paragraph (l); and
■ e. Adding paragraph (m).

The additions and revisions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents, brokers, and web-brokers to—

* * * * *

(c) *Enrollment through the Exchange.* A qualified individual may be enrolled in a QHP through the Exchange with the assistance of an agent, broker, or web-broker if—

(1) The agent, broker, or web-broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange internet website as described in § 155.405, or ensures that the eligibility application information is submitted for an eligibility determination through the Exchange-approved web service subject to meeting the requirements in paragraphs (c)(3)(ii) and (c)(4)(i)(F) of this section;

* * * * *

(3)(i) When an internet website of a web-broker is used to complete the QHP selection, at a minimum the internet website must:

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), and to the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's internet website for a QHP, prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a Web link to the Exchange website;

* * * * *

(K) Comply with the applicable requirements in § 155.221; and

(L) Not display QHP recommendations based on compensation the agent, broker, or web-broker receives from QHP issuers.

(ii) When an internet website of a web-broker is used to complete the Exchange eligibility application, at a minimum the internet website must:

* * * * *

(4) When an agent or broker, through a contract or other arrangement, uses the internet website of a web-broker to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application in the Federally-facilitated Exchange:

(i) The web-broker who makes the website available must:

(A) Provide HHS with a list of agents and brokers who enter into such a contract or other arrangement to use the

web-broker's website, in a form and manner to be specified by HHS;

* * * * *

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under § 155.260(b), by the agent or broker accessing the internet website, should it become aware of any such potential breach. A web-broker that provides access to its website to complete the QHP selection or the Exchange eligibility application or ability to transact information with HHS to another web-broker website is responsible for ensuring compliance with applicable requirements in paragraph (c)(3) of this section for any web pages of the other web-broker's website that assist consumers, applicants, qualified individuals, and enrollees in applying for APTC and CSRs for QHPs, or in completing enrollment in QHPs, offered in the Exchanges.

(F) When an internet website of a web-broker is used to complete the Exchange eligibility application, obtain HHS approval verifying that all requirements in this section are met.

(ii) HHS retains the right to temporarily suspend the ability of a web-broker making its website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or web-broker under this subpart to assess its compliance with the applicable requirements of this section.

(d) *Agreement.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with the terms of an agreement between the agent, broker, or web-broker and the Exchange under which the agent, broker, or web-broker at least:

* * * * *

(2) Receives training in the range of QHP options and insurance affordability programs, except that a licensed agent or broker entity that registers with the Federally-facilitated Exchange in its capacity as a business organized under the laws of a State, and not as an individual person, and direct enrollment technology providers are exempt from this requirement; and

* * * * *

(e) *Compliance with State law.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with applicable State law related to agents, brokers, or web-brokers including applicable State law related to confidentiality and conflicts of interest.

(f) * * *

(1) An agent, broker, or web-broker may terminate its agreement with HHS by sending to HHS a written notice at least 30 days in advance of the date of intended termination.

(2) The notice must include the intended date of termination, but if it does not specify a date of termination, or the date provided is not acceptable to HHS, HHS may set a different termination date that will be no less than 30 days from the date on the agent's, broker's, or web-broker's notice of termination.

(3) Prior to the date of termination, an agent, broker, or web-broker should—

(i) Notify applicants, qualified individuals, or enrollees that the agent, broker, or web-broker is assisting, of the agent's, broker's, or web-broker's intended date of termination;

* * * * *

(4) When the agreement between the agent, broker, or web-broker and the Exchange under paragraph (d) of this section is terminated under paragraph (f) of this section, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(g) * * *

(1) If, in HHS' determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's, broker's, or web-broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent, broker, or web-broker may be determined noncompliant if HHS finds that the agent, broker, or web-broker violated—

* * * * *

(iii) Any State law applicable to agents, brokers, or web-brokers, as required under paragraph (e) of this section, including but not limited to State laws related to confidentiality and conflicts of interest; or

(iv) Any Federal law applicable to agents, brokers, or web-brokers.

* * * * *

(3)(i) Except as provided in paragraph (g)(3)(ii) of this section, HHS will notify the agent, broker, or web-broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(ii) HHS may immediately terminate the agreement for cause upon notice to the agent or broker without any further opportunity to resolve the matter if an agent or broker fails to maintain the appropriate license under State law as an agent, broker, or insurance producer in every State in which the agent or broker actively assists consumers with applying for advance payments of the premium tax credit or cost-sharing reductions or with enrolling in QHPs through the Federally-facilitated Exchanges.

(4) After the applicable period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b)(2) will also be terminated through the process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally

identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(5) * * *

(i)(A) If HHS reasonably suspects that an agent, broker, or web-broker may have may have engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for up to 90 calendar days. Suspension will be effective on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the suspension of the agreements.

(B) The agent, broker, or web-broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent, broker, or web-broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 30 days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If there is a finding or determination by a Federal or State entity that an agent, broker, or web-broker engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm, using personally identifiable information of Exchange enrollees or applicants or in connection with an Exchange enrollment or application, HHS will terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the termination of the agreements.

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(i)(B) or (g)(5)(ii) of this section, the agent, broker, or web-broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

* * * * *

(h) * * *

(1) *Request for reconsideration.* An agent, broker, or web-broker whose agreement with the Federally-facilitated Exchange has been terminated may request reconsideration of such action in the manner and form established by HHS.

(2) *Timeframe for request.* The agent, broker, or web-broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written notice from HHS.

(3) *Notice of reconsideration decision.* The HHS reconsideration entity will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS' final determination.

* * * * *

(i) *Use of agents' and brokers' and web-brokers' internet websites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents, brokers, and web-brokers to use an internet website to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

(j) * * *

(1) An agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

* * * * *

(3) If an agent, broker, or web-broker fails to provide correct information, he, she, or it will nonetheless be deemed in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent, broker, or web-broker acted in good faith.

(k) * * *

(1) If HHS determines that an agent, broker, or web-broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent, broker, or web-broker—

* * * * *

(2) HHS will notify the agent, broker, or web-broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section as part of the termination notice issued under paragraph (g) of this section and, after 30 calendar days from the date of the notice, may impose the penalty if the agent, broker, or web-broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(l) *Application to State Exchanges using a Federal platform.* An agent, broker, or web-broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using the Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

(m) *Web-broker agreement suspension, termination, and denial and information collection.* (1) A web-broker's agreement executed under paragraph (d) of this section, may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, based on the actions of its officers, employees, contractors, or agents, whether or not the officer, employee, contractor, or

agent is registered with the Exchange as an agent or broker.

(2) A web-broker's agreement executed under paragraph (d) of this section may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, if it is under the common ownership or control or is an affiliated business of another web-broker that had its agreement suspended or terminated under paragraph (g) of this section.

(3) The Exchange may collect information from a web-broker during its registration with the Exchange under paragraph (d)(1) of this section, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate ownership and leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the Federally-facilitated Exchange as web-brokers.

■ 17. Section 155.221 is amended by—

■ a. Revising the section heading;

■ b. Redesignating paragraphs (a), (b), and (c) as paragraphs (e), (f), and (g), respectively;

■ c. Adding paragraphs (a), (b), (c), and (d);

■ d. Revising newly redesignated paragraph (e), paragraph (f) introductory text, paragraphs (f)(2), (3), (4), (6) and (7), and paragraph (g); and

■ e. Adding paragraph (h).

The revisions and additions read as follows:

§ 155.221 Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.

(a) *Direct enrollment entities.* The Federally-facilitated Exchanges will permit the following entities to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law:

(1) QHP issuers that meet the applicable requirements in this section and § 156.1230 of this subchapter; and

(2) Web-brokers that meet the applicable requirements in this section and § 155.220.

(b) *Direct enrollment entity requirements.* For the Federally-facilitated Exchanges, a direct enrollment entity must:

(1) Display and market QHPs and non-QHPs on separate website pages on its non-Exchange website;

(2) Prominently display a standardized disclaimer in the form and manner provided by HHS;

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection; and

(5) Comply with applicable Federal and State requirements.

(c) *Direct enrollment entity application assister requirements.* For the Federally-facilitated Exchanges, to the extent permitted under state law, a direct enrollment entity may permit its direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such direct enrollment entity ensures that each of its direct enrollment entity application assisters meets the requirements in § 155.415(b).

(d) *Federally-facilitated Exchange direct enrollment entity suspension.* HHS may immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(e) *Third parties to perform audits of direct enrollment entities.* A direct enrollment entity must engage an independent, third-party entity to conduct an initial and annual review to demonstrate the direct enrollment entity's operational readiness and compliance with applicable direct enrollment entity requirements in accordance with paragraph (b)(4) of this section prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection. The third-party entity will be a downstream or delegated entity of the direct enrollment entity that participates or wishes to participate in direct enrollment.

(f) *Third-party auditor standards.* A direct enrollment entity must satisfy the requirement to demonstrate operational readiness under paragraph (e) of this section by engaging a third-party entity that executes a written agreement with the direct enrollment entity under which the third-party entity agrees to comply with each of the following standards:

* * * * *

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that direct enrollment entities are in compliance with the applicable privacy and security standards and other applicable requirements;

(3) Collects, stores, and shares with HHS all data related to the third-party entity's audit of direct enrollment entities in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and complies with the privacy and security standards HHS adopts for direct enrollment entities as required in accordance with § 155.260;

(4) Discloses to HHS any financial relationships between the entity and individuals who own or are employed by a direct enrollment entity for which it is conducting an operational readiness review;

* * * * *

(6) Ensures, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (e) of this section;

(7) Permits access by the Secretary and the Office of the Inspector General or their designees in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of a direct enrollment entity's obligations in accordance with standards under paragraph (e) of this section until 10 years from the date of creation of a specific audit; and

* * * * *

(g) *Multiple auditors.* A direct enrollment entity may engage multiple third-party entities to conduct the audit under paragraph (e) of this section.

(h) *Application to State Exchanges using a Federal platform.* A direct enrollment entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for

advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

■ 18. Section 155.415 is revised to read as follows:

§ 155.415 Allowing issuer or direct enrollment entity application assisters to assist with eligibility applications.

(a) *Exchange option.* An Exchange, to the extent permitted by State law, may permit issuer application assisters and direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs, provided that such issuer application assisters or direct enrollment entity application assisters meet the requirements set forth in paragraph (b) of this section.

(b) *Application assister requirements.* If permitted by an Exchange under paragraph (a) of this section, and to the extent permitted by State law, an issuer may permit its issuer application assisters and a direct enrollment entity may permit its direct enrollment entity application assisters to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such issuer or direct enrollment entity ensures that each of its issuer application assisters or direct enrollment entity application assisters at least—

(1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations, and for application assisters providing assistance in the Federally-facilitated Exchanges or a State Exchange using the Federal platform, the assisters must fulfill this requirement by completing registration and training in a form and manner to be specified by HHS;

(2) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260; and

(3) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including any State licensure laws applicable to the functions to be performed by the issuer application assister or direct enrollment entity application assister, as well as State law related to confidentiality and conflicts of interest.

■ 19. Section 155.420 is amended—

■ a. By revising paragraphs (a)(5) and (b)(2)(iv);

■ b. In paragraph (d)(6)(ii) by removing ''; or'' and adding in its place '';'';

■ c. In paragraph (d)(6)(iii) by removing ''.'' and adding in its place '';'';

■ d. In paragraph (d)(6)(iv) by removing '';'' and adding in its place ''; or''; and

■ e. By adding paragraph (d)(6)(v).

The addition reads as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(5) *Prior coverage requirement.* Qualified individuals who are required to demonstrate coverage in the 60 days prior to a qualifying event can either demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) or demonstrate that they had coverage as described in paragraphs (d)(1)(iii) or (iv) of this section for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; are an Indian as defined by section 4 of the Indian Health Care Improvement Act; or lived for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, in a service area where no qualified health plan was available through the Exchange.

(b) * * *

(2) * * *

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, or becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

* * * * *

(d) * * *

(6) * * *

(v) At the option of the Exchange, the qualified individual, or his or her dependent—

(A) Experiences a decrease in household income;

(B) Is newly determined eligible by the Exchange for advance payments of the premium tax credit; and

(C) Had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for one or more days during the 60 days preceding the date of the financial change.

* * * * *

■ 20. Section 155.605 is amended by adding paragraph (e)(5) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(e) * * *

(5) *General hardship.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 12, 2018, entitled, ''Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)'' (see *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf*) and in IRS Notice 2019–05 (see *https://www.irs.gov/pub/irs-drop/n-19-05.pdf*), for the 2018 tax year.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 21. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 22. Section 156.20 is amended by adding the definition of ''Generic'' in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Generic means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved.

* * * * *

■ 23. Section 156.130 is amended by adding paragraph (h) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(h) *Use of drug manufacturer coupons.* For plan years beginning on or after January 1, 2020:

(1) Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(2) [Reserved]

■ 24. Section 156.1230 is amended by—

■ a. Removing and reserving paragraph (a)(2);

■ b. Revising paragraph (b)(1);

■ c. Removing paragraph (b)(2); and

■ d. Redesignating paragraph (b)(3) as (b)(2).

The revisions read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

(a) * * *

(2) [Reserved]

(b) * * *

(1) The QHP issuer must comply with applicable requirements in § 155.221 of this subchapter.

* * * * *

Dated: March 26, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–08017 Filed 4–18–19; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1714–P]

RIN 0938–AT71

Medicare Program; FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the hospice wage index, payment rates, and cap amount for fiscal year 2020. This rule proposes to rebase the continuous home care, general inpatient care, and the inpatient respite care per diem payment rates in a budget-neutral manner to more accurately align Medicare payments with the costs of providing care. In addition, this rule proposes to modify the election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patient under a hospice election. Finally, this rule proposes changes to the Hospice Quality Reporting Program.

DATES: *Comments:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 18, 2019.

ADDRESSES: In commenting, refer to file code CMS–1714–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1714–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1714–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general questions about hospice payment policy, send your inquiry via email to: *hospicepolicy@cms.hhs.gov.* Debra Dean-Whittaker, (410) 786–0848 for questions regarding the CAHPS® Hospice Survey. Cindy Massuda, (410) 786–0652 for questions regarding the hospice quality reporting program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. Wage index addenda will be available only through the internet on our website at: (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html.*)

I. Executive Summary

A. Purpose

This rule proposes updates to the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2020, as required under section 1814(i) of the Social Security Act (the Act). This rule proposes to rebase the continuous home care (CHC), general inpatient care (GIP), and inpatient respite care (IRC) per diem payment rates in a budget neutral manner to more accurately align payments with the costs of providing care, using the hospice payment reform authority under section 1814(i)(6) of the Act. This rule also proposes a change to the hospice wage index to remove the 1-year lag in data by using the current year's hospital wage data to establish the hospice wage index. In addition, this rule proposes to modify the hospice election statement by requiring an addendum that includes information aimed at increasing coverage transparency for patients under a hospice election. Finally, this rule proposes changes to the Hospice Quality Reporting Program.

B. Summary of the Major Provisions

Section III.A of this proposed rule describes the FY 2020 hospice per diem payment rebasing methodology, cost reports and calculations. Using the hospice payment reform authority under section 1814(i)(6) of the Act, section III.A.3 proposes to rebase the FY 2020 per diem payment rates for CHC, IRC, and GIP levels of care. As required in section 1814(i)(6)(D)(ii) of the Act, any changes to hospice payment rates must be done in a budget neutral manner. As such, section III.A.3 also proposes a reduction to the routine home care (RHC) payment amounts for FY 2020 in order to maintain overall budget neutrality. Section III.B.1 of this proposed rule proposes to eliminate the 1-year lag of the pre-floor, pre-reclassified hospital wage index that is used in calculating the hospice wage index. Section III.B.2 proposes updates to the hospice wage index and makes the application of the updated wage data budget neutral for all four levels of hospice care. In section III.B.4 of this proposed rule, we discuss the proposed FY 2020 hospice payment update percentage of 2.7 percent. Section III.B.5 outlines the proposed FY 2020 hospice payment rates that result from the policies proposed in section III.A. Section III.B.6 of this proposed rule updates the hospice cap amount for FY 2020 by the hospice payment update percentage discussed in section III.B.4 of this rule. Section III.C proposes to modify the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election by notifying beneficiaries if there are services that will not be covered by the hospice.

In addition, section III.D describes a request for information (RFI) as it relates to the Medicare Fee-For-Service (FFS) Hospice benefit and coordination of care at end-of-life. Finally, in section III.E of this proposed rule, we discuss updates to the Hospice Quality Reporting Program (HQRP), including: The development of claims-based and outcome measures, measure concepts, and the hospice assessment tool. We also provide updates on the public reporting change for the ''Hospice Visits When Death is Imminent'' measure pair, the posting of publicly available government data to the CMS Hospice Compare website and the CAHPS® Hospice Survey.

C. Summary of Impacts

The overall economic impact of this proposed rule is estimated to be $540

million in increased payments to hospices for FY 2020.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. Hospice is compassionate beneficiary and family/caregiver-centered care for those who are terminally ill.

As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. The regulations at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

Under the Medicare hospice benefit, the election of hospice care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group is essential in the seamless provision of services. These hospice services are provided primarily in the individual's home. The hospice interdisciplinary group works with the beneficiary, family, and caregivers to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition. The beneficiary's care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) as the individual approaches the end of life.

If, in the judgment of the hospice interdisciplinary team, which includes the hospice physician, the patient's symptoms cannot be effectively managed at home, then the patient is eligible for general inpatient care (GIP), a more medically intense level of care. GIP must be provided in a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital. GIP is provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home and continue to receive routine home care. Limited, short-term, intermittent, inpatient respite care (IRC) is also available because of the absence or need for relief of the family or other caregivers. Additionally, an individual can receive continuous home care (CHC) during a period of crisis in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with our regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices must comply with applicable civil rights laws,[1] including Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: *http://www.hhs.gov/ocr/civilrights.*

[1] Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, Section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

B. Services Covered by the Medicare Hospice Benefit

Coverage under the Medicare Hospice benefit requires that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare-certified hospice program. These covered services include: Nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); continuous home care during periods of crisis, and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, that hospice program; and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (described in section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

Upon the implementation of the hospice benefit, the Congress also expected hospices to continue to use volunteer services, though these services are not reimbursed by Medicare (see section 1861(dd)(2)(E) of the Act). As stated in the FY 1983 Hospice Wage Index and Rate Update proposed rule (48 FR 38149), the hospice interdisciplinary group should comprise paid hospice employees as well as hospice volunteers, and that ''the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary

spirit of hospices.'' This expectation supports the hospice philosophy of community based, holistic, comprehensive, and compassionate end-of-life care.

C. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in 42 CFR part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (RHC, CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is to include all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today with some adjustments, as noted below.

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) amended section 1814(i)(1)(C) of the Act and provided changes in the methodology concerning updating the daily payment rates based on the hospital market basket percentage increase applied to the payment rates in effect during the previous federal fiscal year.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established that updates to the hospice payment rates beginning FY 2002 and subsequent FYs be the hospital market basket percentage increase for the FY.

3. FY 1998 Hospice Wage Index Final Rule

The FY 1998 Hospice Wage Index final rule (62 FR 42860), implemented a new methodology for calculating the hospice wage index and instituted an annual Budget Neutrality Adjustment Factor (BNAF) so aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index.

4. FY 2010 Hospice Wage Index Final Rule

The FY 2010 Hospice Wage Index and Rate Update final rule (74 FR 39384) instituted an incremental 7-year phase-out of the BNAF beginning in FY 2010 through FY 2016. The BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value, but was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act is subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) of the Act.

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures specified by the Secretary of the Department of Health and Human Services (the Secretary), for FY 2014 and subsequent FYs. Beginning in FY 2014, hospices that fail to report quality data have their market basket percentage increase reduced by 2 percentage points.

Section 1814(a)(7)(D)(i) of the Act, as added by section 3132(b)(2) of the PPACA, required, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, we finalized in the FY 2011 Hospice Wage Index final rule (75 FR 70435) that the 180th day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the PPACA, authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the PPACA could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data collected could be used to revise the methodology for determining the payment rates for RHC and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, we were required to consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

In the FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) we announced that beginning in 2012, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology, within certain limits. We allowed existing hospices the option of having their cap calculated through the original streamlined methodology, also within certain limits. As of FY 2012, new hospices have their cap determinations calculated using the patient-by-patient proportional methodology. If a hospice's total Medicare payments for the cap year exceed the hospice aggregate cap, then the hospice must repay the excess back to Medicare.

7. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50452) finalized a requirement that the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). Similar to the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation within 5 calendar days after the effective date of the discharge/revocation (unless the hospice has already filed a final claim) through the submission of a final claim or a Notice of Termination or Revocation (NOTR).

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50479) also finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians.

In addition, the FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50496) provided background, eligibility criteria, survey respondents,

and implementation of the Hospice Experience of Care Survey for informal caregivers. Hospice providers were required to begin using this survey for hospice patients as of 2015.

Finally, the FY 2015 Hospice Wage Index and Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that failed to timely submit their aggregate cap determinations had their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

8. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days of care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment update rather than using the consumer price index for urban consumers (CPI–U) for medical care expenditures.

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we created two different payment rates for RHC that resulted in a higher base payment rate for the first 60 days of hospice care and a reduced base payment rate for subsequent days of hospice care. We also created a Service Intensity Add-on (SIA) payment payable for services during the last 7 days of the beneficiary's life, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by a registered nurse (RN) or social worker that occurs during the last 7 days (80 FR 47177).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47186) implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016 and before October 1, 2025 is updated by the hospice payment update percentage rather than using the CPI–U. This was applied to the 2016 cap year, starting on November 1, 2015 and ending on October 31, 2016. In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the fiscal year for FY 2017 and thereafter. Finally, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47144) clarified that hospices must report all diagnoses of the beneficiary on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52160), we finalized several new policies and requirements related to the HQRP. First, we codified our policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQRP measures as part of the NQF's re-endorsement process, we would continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking. We would continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the HQRP; determinations about what constitutes a substantive versus non-substantive change would be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQRP for the FY 2019 payment determination and subsequent years: Hospice Visits when Death is Imminent Measure Pair and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission (81 FR 52173). The data collection mechanism for both of these measures is the HIS, and the measures were effective April 1, 2017. Regarding the CAHPS® Hospice Survey, we finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS®) requirements due to newness (81 FR 52182). The exemption is determined by CMS and is for 1 year only.

D. Trends in Medicare Hospice Utilization

Since the implementation of the hospice benefit in 1983, there has been substantial growth in hospice utilization. The number of Medicare beneficiaries receiving hospice services has grown from 513,000 in FY 2000 to over 1.5 million in FY 2018. Medicare hospice expenditures have risen from $2.8 billion in FY 2000 to approximately $18.7 billion in FY 2018. CMS' Office of the Actuary (OACT) projects that hospice expenditures are expected to continue to increase, by approximately 8.5 percent annually, reflecting an increase in the number of Medicare beneficiaries, more beneficiary awareness of the Medicare hospice benefit for end-of-life care, and a growing preference for care provided in home and community-based settings.

As a part of our ongoing analysis of hospice utilization trends, we examined the distribution of total hospice days by level of care. A review of claims over the last 10 years shows that RHC remains the highest utilized level of care, accounting for an average of 97.6 percent of total hospice days; GIP accounting for 1.7 percent of total hospice days; CHC accounting for 0.4 percent of total hospice days; and, IRC accounting for 0.3 percent of total hospice days.

There have also been notable changes in the diagnosis patterns among Medicare hospice enrollees. At the time of the implementation of the Medicare hospice benefit, cancer diagnoses were the most frequently reported diagnoses. However, there has been a significant increase in the reporting of neurologically-based diagnoses, including Alzheimer's disease, which has been the top-reported diagnosis on hospice claims since 2014. The increase in the reporting of neurological conditions as the principal diagnosis on hospice claims corresponds to a clarification in the FY 2014 hospice final rule (78 FR 48242) on diagnosis reporting where ''debility'' and ''adult failure to thrive'' are no longer permitted to be reported as principal diagnosis codes on hospice claims. Our ongoing analysis of diagnosis reporting trends finds that neurological and organ-based failure conditions remain top-reported principal diagnoses.

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47201), we clarified that hospices are to report all diagnoses identified in the initial and comprehensive assessments on hospice claims, whether related or unrelated to the terminal prognosis of the individual, effective October 1, 2015. Analysis of FY 2018 hospice claims show that 100 percent of claims included at least one diagnosis, 90.3 percent of claims included at least two

diagnoses, and 82.1 percent of claims included at least three diagnoses.

Finally, we examined hospice trends relating to hospice length of stay. The number of days that a hospice beneficiary receives care under a hospice election is referred to as the hospice length of stay (LOS). Length of stay can be analyzed in several ways. Total *lifetime* length of stay includes the sum of all days of hospice care across all hospice elections. This would mean if a beneficiary had one hospice election, was discharged alive, and then reelected the benefit at a later date, the sum of both elections would count towards their lifetime length of stay. Average length of stay refers to the number of hospice days during a single hospice election at the date of live discharge or death. The median length of stay reflects the 50th percentile and is often the most meaningful comparison measure for evaluating LOS data as the total lifetime length of stay and the average length of stay are affected by extremely short and extremely long lengths of stay. Table 1 lists the clinical categories of principal diagnoses reported on hospice claims along with the corresponding number of decedents, as well as the average, total lifetime and median lengths of stay.

TABLE 1—AVERAGE LENGTH OF STAY IN DAYS FOR HOSPICE USERS IN FY 2018

Category	Number of hospice users who are discharged at the end of FY 2018	Average lifetime length of stay	Median lifetime length of stay	Number of elections (elections ending in FY 2018)	Average length of election	Median length of election
Alzheimer's, Dementia, and Parkinson's	203,349	167.4	50	215,547	124.9	37
CVA/Stroke	55,321	142.7	30	58,457	109.7	24
Cancers	286,131	53.6	17	303,507	46.0	16
Chronic Kidney Disease	27,527	43.9	8	28,740	34.6	7
Heart (CHF and Other Heart Disease)	203,613	106.0	24	216,161	83.7	20
Lung (COPD and Pneumonias)	114,399	103.9	18	122,579	79.6	16
Other	335,777	78.7	13	352,288	61.3	12
All Diagnoses	1,226,117	96.6	19	1,297,279	75.3	17

Source: FY 2018 hospice claims data from CCW on January 29, 2019.
Note(s): Only beneficiaries whose last day of hospice in FY 2018 was not associated with a discharge status code of "30" were counted ("30" indicates they remained in hospice). Lifetime length of stay is determined using all hospice elections over the beneficiary's lifetime.

III. Provisions of the Proposed Rule

A. Proposed Rebasing of the Continuous Home Care, Inpatient Respite Care, and General Inpatient Care Payment Rates for FY 2020

1. Background

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and our regulations in part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment in one of four prospectively-determined rate categories of hospice care (routine home care (RHC), continuous home care (CHC), inpatient respite care (IRC) and general inpatient care (GIP)), based on each day a qualified Medicare beneficiary is under a hospice election. These per diem payments include reimbursement for all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act. There has been little change in the hospice payment structure since the benefit's inception. The per diem rate based on level of care was established in 1983, and this payment structure remains today.

We originally set the base payment rates for each level of care in 1983 using information from a relatively small set (n=26) of hospices that were participating in a CMS hospice demonstration. As a result of technological changes to providing hospice care that have occurred since the early 1980's, as well as changes in the patient population that uses the hospice benefit, it is possible that the current per diem payment rates for the Medicare hospice benefit do not align accurately with the costs of providing care. Since the establishment of the base payment rates, they have been updated through the years to primarily account for inflation, but we have not implemented any large scale changes to reflect non-inflationary changes in cost over time, with the exception of the bifurcation of the RHC payment rate and the creation of the SIA payment finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule for implementation on January 1, 2016 (80 FR 47142).

For over a decade, MedPAC and other organizations reported findings that suggested that the hospice benefit's fixed per-diem payment system was inconsistent with the true variance of service costs over the course of an episode. Specifically, MedPAC cited both academic and non-academic studies, as well as its own analyses (as summarized and articulated in MedPAC's 2002,[2] 2004,[3] 2006,[4] 2008,[5] and 2009[6] Reports to Congress), demonstrating that the intensity of services over the duration of a hospice stay manifests in a 'U-Shaped' pattern (that is, the intensity of services provided is higher both at admission and near death and, conversely, is relatively lower during the middle period of the hospice episode). Since hospice care is most profitable during the long, low-cost middle portions of an episode, longer episodes have very

[2] Medicare Payment Advisory Commission (MedPAC). ''Report to the Congress: Medicare Payment Policy.'' Washington, DC. March 2002. P. 48. *http://www.medpac.gov/docs/default-source/reports/Mar02_Entire_report.pdf.*

[3] Medicare Payment Advisory Commission (MedPAC). ''Report to the Congress: Medicare Payment Policy.'' Washington, DC. March 2004. *http://www.medpac.gov/docs/default-source/reports/Mar04_Entire_reportv3.pdf?sfvrsn=0.*

[4] Medicare Payment Advisory Commission (MedPAC). ''Report to the Congress: Medicare Payment Policy.'' Washington, DC. March 2006. *http://www.medpac.gov/docs/default-source/reports/Mar06_EntireReport.pdf?sfvrsn=0.*

[5] Medicare Payment Advisory Commission (MedPAC). ''Report to the Congress: Medicare Payment Policy.'' Washington, DC. March 2008. *http://www.medpac.gov/docs/default-source/reports/mar08_entirereport.pdf?sfvrsn=0.*

[6] Medicare Payment Advisory Commission (MedPAC). ''Report to the Congress: Medicare Payment Policy.'' Washington, DC. March 2009. P 347 *http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf?sfvrsn=0.*

profitable, long middle segments. In its March 2009 report, ''Reforming Medicare's Hospice Benefit,'' As mentioned previously, this led to CMS finalizing a bifurcated payment rate for RHC level of care in the FY 2016 (80 FR 47172) hospice final rule. These dual RHC payment rates were derived from observed resource utilization reflecting the cost of providing care for the clinical service (labor) components of the RHC across the entire episode, that would produce higher payments during times when service is more intensive (the beginning of a stay or the end of life) and produce lower payments during times when service is less intensive (such as the ''middle period'' of the stay). For the establishment of the dual RHC rates we used visit intensity as a close proxy for the reasonable cost of providing hospice care absent data on the non-labor components of the RHC rate, such as drugs and DME. In addition to the dual RHC payment rates, CMS also finalized a Service Intensity Add-on (SIA) payment payable for services during the last 7 days of the beneficiary's life, equal to the CHC hourly payment rate multiplied by the amount of direct patient care provided by a registered nurse (RN) or social worker that occurs during the last 7 days (80 FR 47177). While we made changes to the RHC payment rate based on resource utilization and established an SIA payment to account for differences in resource use throughout the course of hospice care, we did not make any changes to the per diem payment rates for CHC, IRC or GIP. Likewise, the dual RHC rates did not reflect the total costs of providing hospice care given the lack of more comprehensive information on the costs associated with the services provided by hospices to Medicare beneficiaries by level of care at that time.

Hospices are paid per day, regardless of whether any services are provided to a hospice patient on any given day. The CHC level of care is paid based on an hourly rate when a hospice patient, who is not in an inpatient facility, receives hospice care consisting predominantly of nursing care on a continuous basis at home. The hospice must provide a minimum of 8 hours of care in a 24 hour period in order for such services to be covered as CHC. The GIP level of care is a day in which a hospice patient receives care in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings. The IRC level of care is short-term care provided only when necessary to relieve the family members or other persons caring for the hospice patient at home. IRC can be provided for up to 5 consecutive days.

While hospices must provide all levels of care to meet the hospice Conditions of Participation (CoPs), there is much lower utilization of CHC, IRC, and GIP compared to RHC. As part of our ongoing reform work, we analyzed the trends in hospice days and payments by level of care. Our analysis found that between FY 2009 and FY 2018 RHC days as a percent of total hospice days increased from 97.2 percent to 98.2 percent. Conversely, during this time frame CHC and GIP days as a percent of total hospice days decreased. CHC days as a percent of total hospice days decreased by half, and in FY 2018, CHC was only 0.2 percent of total hospice days compared to 0.4 percent in FY 2009. GIP days as a percent of total hospice days decreased from 2.1 percent in FY 2009 to 1.3 percent in FY 2018. Finally, the percent of IRC days remained relatively constant from FY 2009–FY 2018 at 0.3 percent of total hospice days in FY 2018. The results were similar for the percent of payments by level of care. RHC payments as a percent of total hospice payments increased from 89.2 percent in FY 2009 to 93.4 percent in FY 2018. CHC payments as a percent of total payments decreased from 1.9 percent of payments in FY 2009 to 1.0 percent in FY 2018. GIP payments decreased from 8.7 percent of total hospice payments in FY 2009 to 5.3 percent in FY 2018. Finally, IRC payments as a percent of total hospice payments increased slightly to 0.3 percent in 2018 from 0.2 percent in 2009.[7] Figure 1 shows the trends of total hospice days by level of care for FYs 2009–2018 and Figure 2 shows the trends of total hospice payments by level of care for FYs 2009–2018.

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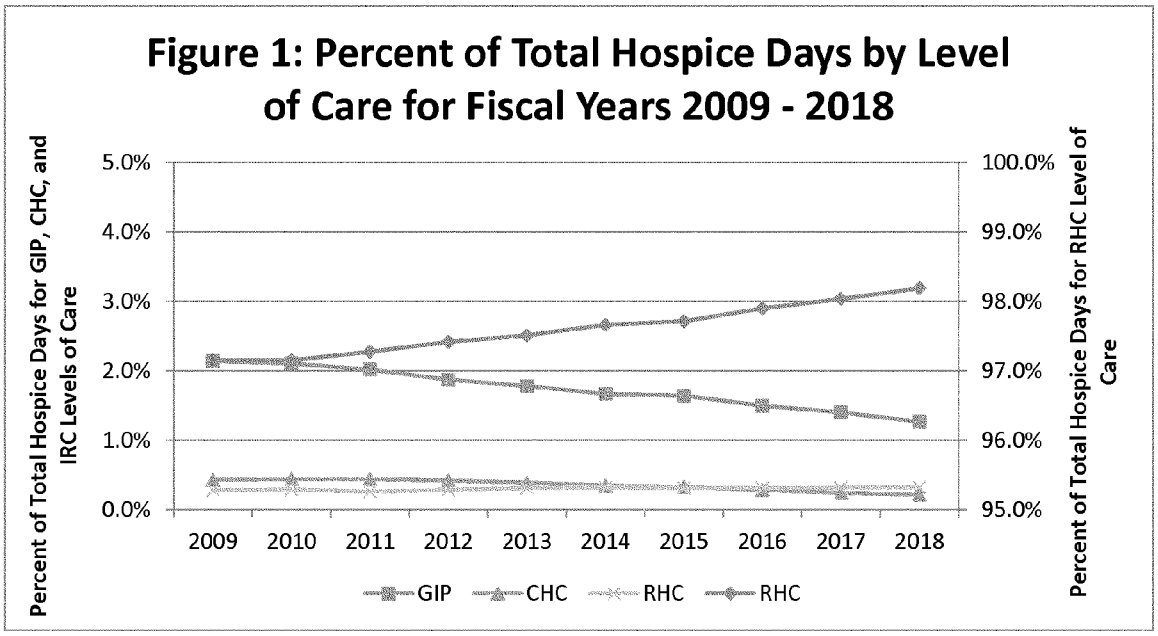
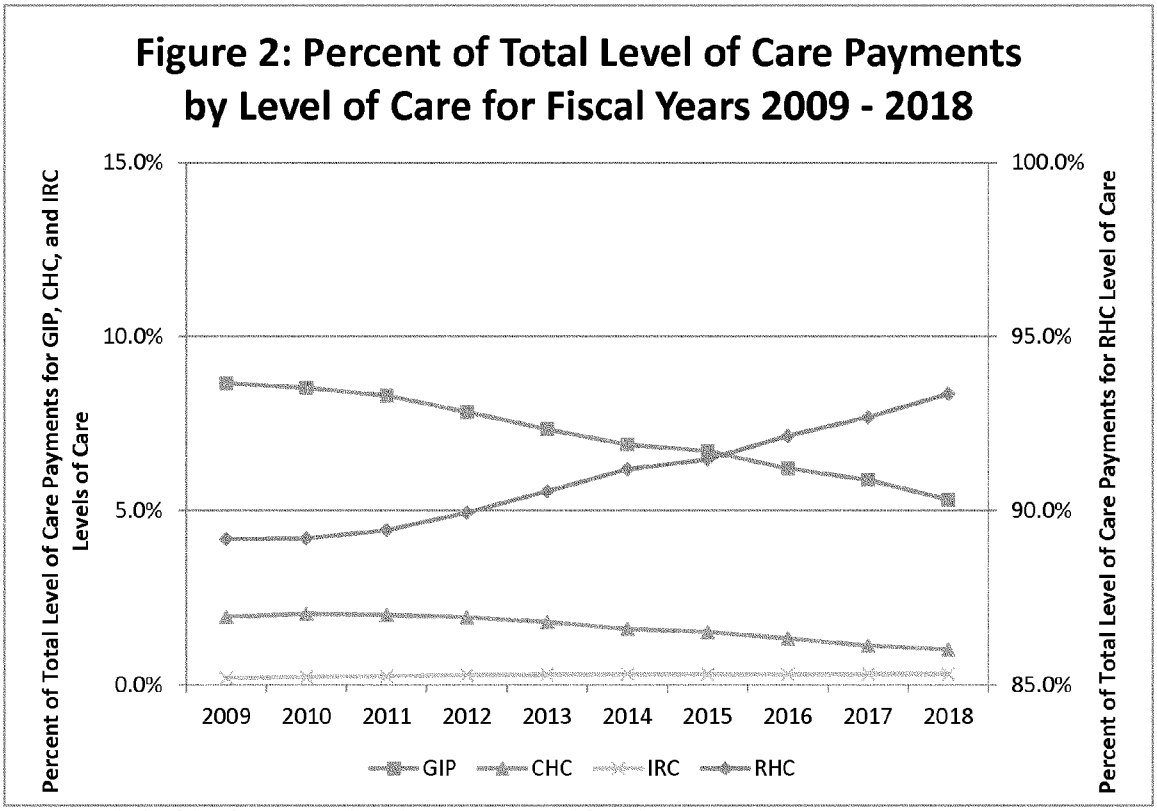
[7] FY 2009 through FY 2018 hospice claims data, accessed from the Chronic Conditions Data Warehouse (CCW) on January 3, 2019.



Source: Analysis of data for FY 2009 through FY 2018 accessed from the CCW on January 3, 2019.

Note(s): Line items were assigned to a level of care using the revenue codes 0651(RHC), 0652 (CHC), 0655 (IRC) and 0656 (GIP). RHC, IRC, and GIP days were counted by adding the revenue units for any line item with those revenue codes. CHC days were counted by adding up the number of line items with revenue code 0652. Payments for each line item were summed.



Source: Analysis of data for FY 2009 through FY 2018 accessed from the CCW on January 3, 2019.

Note(s): Line items were assigned to a level of care using the revenue codes 0651(RHC), 0652 (CHC), 0655 (IRC) and 0656 (GIP). RHC, IRC, and GIP days were counted by adding the revenue units for any line item with those revenue codes. CHC days were counted by adding up the number of line items with revenue code 0652. Payments for each line item were summed.

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As discussed previously in this proposed rule, section 1814(i)(6) of the Act, as amended by section 3132(a)(1)(B) of the Affordable Care Act, authorizes the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The data collected may be used to revise the methodology for determining the payment rates for RHC and other hospice services (in a budget-neutral manner in the first year), no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. Furthermore, section 3132(a)(1)(C) of the Affordable Care Act specifies that the Secretary may collect additional data and information on cost reports, claims, or other mechanisms as the Secretary determines to be appropriate.

The Secretary is required to consult with hospice programs and the MedPAC regarding additional data collection and payment reform options. We have transparently conducted payment reform analysis and have released research findings to the public in our 2013 and 2014 Technical Reports,[8] [9] as well as in the FYs 2014 and 2015 Hospice Wage Index and Payment Rate Update final rules (78 FR 48234 and 80 FR 50452). These research findings and concepts provided a basis for the initial step toward hospice payment reform.

Based on stakeholder suggestions, we began collecting additional information on the hospice claims form as of April 1, 2014.[10] These changes include the reporting of line-item visit data for hospice staff providing GIP to hospice patients in skilled nursing facilities (site of service Healthcare Common Procedure Coding System (HCPCS) code Q5004) or in hospitals (site of service HCPCS codes Q5005, Q5007, Q5008). This includes visits by hospice nurses, aides, social workers, physical therapists, occupational therapists, and speech-language pathologists, on a line-item basis, with visit and visit length reported as is done for RHC and CHC. It also includes certain calls by hospice social workers (as described in CR 6440, Transmittal 1738),[11] on a line-item basis, with call and call length reported, as is done for RHC and CHC. However, we did not change the existing GIP visit reporting requirements when the site of service is a hospice inpatient unit (site of service HCPCS code Q5006). Only visits/calls made by the paid hospice staff are to be reported; hospices do not report visits by non-hospice staff. Additionally, hospices are required to report visits and length of visits (rounded to the nearest 15 minute increment), for nurses, aides, social workers, and therapists who are employed by the hospice, that occur on the date of death, after the patient has passed away. Finally, these changes included the requirement that hospice agencies report injectable and non-injectable prescription drugs for the palliation and management of the terminal illness and related conditions on their claims. Both injectable and non-injectable prescription drugs would be reported on claims on a line-item basis per fill, based on the amount dispensed by the pharmacy. Over-the-counter drugs would not be reported on the claim. However, we removed the requirement to report detailed drug data on the hospice claim as a way to reduce burden for hospices. Instead, hospices are now only required to report total durable medical equipment (DME) and medication charges on the claim. This change became effective October 1, 2018.

Effective for cost reporting periods beginning on or after October 1, 2014, freestanding hospices are required to file the revised hospice cost report (Form CMS–1984–14).[12] Provider-based hospices began using the revised cost report form for cost reporting periods beginning on or after October 1, 2015. The revised cost report expands data collection requirements to supply greater detail related to hospice costs by level of care. Hospices are required to report all direct patient care costs by multiple cost categories into the respective level of care. Within the revised cost report changes in 2014, there were modifications in the manner in which general service costs and statistical information is accumulated by the hospice and an expansion of the general service cost centers. Instructions for completing the freestanding hospice cost report (Form CMS–1984–14) are found in the Medicare Provider Reimbursement Manual—Part 2, Chapter 43.[13]

In the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47142) we stated that we received many suggestions for ways to improve data collection to support larger payment reform efforts in the future and that we expected to analyze additional claims and cost report data reported by hospices to determine whether additional regulatory proposals to reform and strengthen the Medicare hospice benefit would be warranted (80 FR 47161). Likewise, MedPAC, the Government Accountability Office (GAO), and the Office of the Inspector General (OIG) have all recommended that CMS collect more comprehensive data to better evaluate trends in utilization of the Medicare hospice benefit.

We continued to analyze hospice claims and cost report data to determine whether additional changes need to be made to more accurately align hospice payment with the costs of providing care. Specifically, we have continued to examine whether there is a misalignment between payment and costs for CHC, IRC, and GIP. In its March 2018 Report to the Congress, MedPAC stated Medicare's payment rates for the CHC, IRC and GIP levels of care appear to be lower than the average and median costs per day for freestanding providers and suggested that rebalancing the payment rates may be warranted.[14]

Additionally, we received public comments on past rules that indicated the payment rates for CHC, IRC and GIP are much different from the average costs of providing those levels of care. Specifically, several commenters expressed concerns regarding the rates for these levels of care being insufficient to acquire and maintain contracts for inpatient levels of care. In response to the FY 2015 Hospice Wage Index and Payment Rate Update proposed rule (79 FR 26538), a commenter suggested that hospices have difficulty contracting for respite care in many areas because the hospice respite rate may be $5 to $50 less per day than the facility's Medicaid rate. This commenter also stated that nursing facilities in many states do not want to accept less than their Medicaid

[8] Medicare Hospice Payment Reform: Hospice Study Technical Report. Cambridge, MA. April 2013. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Study-Technical-Report.pdf.*

[9] Medicare Hospice Payment Reform: Analyses to Support Payment Reform. Cambridge, MA. May 2014. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-Study-Technical-Report.pdf.*

[10] CMS Transmittal 2864. ''Additional Data Reporting Requirements for Hospice Claims.'' Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2864CP.pdf.*

[11] CR 6440, Transmittal 1738. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1738CP.pdf.*

[12] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1P243.pdf.*

[13] The Provider Reimbursement Manual—Part 2. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html.*

[14] Medicare Payment Advisory Commission (MedPAC). ''Hospice Services.'' *Report to the Congress: Medicare Payment Policy.* Washington, DC. March 2018. P. 341. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch12_sec.pdf?sfvrsn=0.*

room and board rate. In response to the FY 2016 Hospice Wage Index and Payment Rate Update proposed rule (80 FR 25832) one commenter stated that some hospitals do not want to accept the GIP hospice rate which leaves hospices unable to provide the GIP level of care. Finally, in response to the FY 2019 Hospice Wage Index and Payment Rate Update proposed rule (83 FR 20934), one commenter stated that providers have reported that it is more difficult to obtain new GIP contracts with hospitals and skilled nursing facilities and to retain existing contracts as they are renegotiated because the hospice GIP rate is less than the hospital would receive for an acute inpatient stay. Some commenters also suggested that hospices must pay the contracting facility the full daily hospice reimbursement rate in order to secure a contract for inpatient care. The Hospice CoPs at § 418.108 require that inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility. Therefore, hospices that do not provide inpatient care and are unable to negotiate contracts with hospitals or skilled nursing facilities (SNFs) for inpatient level of care are in violation of the hospice CoPs. However, through public comments and anecdotal reports from hospices, we continue to hear that the payment rates for CHC, IRC, and GIP are a significant factor in whether or not hospices can secure the necessary contracts to provide these levels of care.

Using information collected from the revised hospice cost report, for the first time, we are able to estimate hospices' average costs per day by level of care. As required by section 1814(i)(1)(A) of the Act, payment for hospice services must be an amount equal to the costs which are reasonable and related to providing hospice care, or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations. Therefore, given that we now have several years' worth of cost report data from the revised hospice cost report, we calculated the average costs per day by level of care and compared such costs to the per diem payment rates by level of care to determine if there is a misalignment between payment and costs and whether the per diem payment rates for CHC, IRC, and GIP should be rebased. To conduct this analysis, we used a variety of different data sources, including cost reports and hospice claims data. We also used additional sources such as prior hospice final rules that detail wage indices and payment rate updates, as well as the CMS Provider of Services (POS) file. The methodology of this analysis is described below.

2. Methodology and Analysis of Costs per Day for Continuous Home Care, Inpatient Respite Care, and General Inpatient Care

a. Hospice Cost Report Data

Our analysis was based on information obtained from the Healthcare Cost Report Information System (HCRIS). The Hospice Cost Report Data contains cost and statistical data for freestanding and provider-based hospice providers. The dataset is normally updated quarterly and is available on the last day of the month following the quarter's end. To determine the average per-day costs of providing hospice services, we conducted initial analysis of both freestanding and provider-based Medicare hospice cost reports. We used the following HCRIS data files as of December 31, 2018, for cost reports from FY 2017 to support our analyses: [15]

Freestanding Hospices	*http://downloads.cms.gov/Files/hcris/HOSPC14-ALL-YEARS.zip.*
Skilled Nursing Facility (SNF) Based Hospices	*https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year-Items/SNF10-DL-2017.html.*
Home Health Agency (HHA) Based Hospices	*https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year-Items/HHA-DL-2017.html.*
Hospital Based Hospices	*https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year-Items/HOSPITAL10-DL-2017.html.*

The HCRIS data as of December 31, 2018, were downloaded February 2019. To create the initial analytic file, we took a number of data cleaning steps to exclude certain hospices. Specifically, we made the following exclusions: [16]

Exclusion 1: A small number of hospices (as represented by CMS Certification Number (CCN)) had multiple FY 2017 cost reports in the HCRIS cost report data file. For those hospices, we kept the cost report that covered the greatest length of time in FY 2017; [17]

Exclusion 2: We eliminated SNF, HHA, and hospital cost reports that did not contain a hospice CCN; and

Exclusion 3: We eliminated 15 cost reports (as represented by CCN) due to the following reasons:

a. Sometimes within a provider-based cost report, the same CCN was listed multiple times (that is, there might be two separate reports of RHC costs for the same CCN within a provider-based cost report). In order to limit each hospice to one single cost report, we selected the cost report with the highest RHC cost.[18]

b. Sometimes a CCN appeared in a freestanding cost report as well as appeared in a provider-based cost report.

Table 2 below shows the starting sample and the number of hospice cost reports after applying the exclusions listed above.

TABLE 2—NUMBER OF MEDICARE HOSPICE COST REPORTS AFTER EXCLUSIONS

Type of cost report	Starting sample	Exclusion 1	Exclusion 2	Exclusion 3 [19]
Freestanding	3,253	3,213	3,213	3,207
Skilled Nursing Facility (SNF)	14,883	14,068	26	26

[15] Cost reports from FY 2017 had a start date on or after October 1, 2016 and before October 1, 2017.

[16] For the three exclusions, we found information on hospice CCNs using Worksheet S–2 of provider-based cost reports. Specifically, we used information from Worksheet S–2, Part I, line 14 and its subscripts for hospital-based cost reports, Worksheet S–2, Part I, line 12 and its subscripts for SNF based cost reports, and Worksheet S–2, line 3.50 and its subscripts for home health agency cost reports. Additionally, a single provider-based cost report could contain information on multiple hospice CCNs, in which case we considered each hospice CCN as a separate cost report.

[17] We determined the length of the cost report by subtracting the cost reports fiscal year begin date from the cost reports fiscal year end date.

[18] For example, in one home health agency-based cost report, the home health agency reported costs for the same hospice CCN three different times on the same cost report.

TABLE 2—NUMBER OF MEDICARE HOSPICE COST REPORTS AFTER EXCLUSIONS—Continued

Type of cost report	Starting sample	Exclusion 1	Exclusion 2	Exclusion 3 [19]
Home Health Agency (HHA)	10,227	10,090	476	473
Hospital	5,480	5,413	425	419

Next, we constructed a series of flags to identify cost reports that did not fill out fields that we would expect hospices to report (for example, nursing services). We identified those cost report fields using information from the Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14, Transmittal 3, dated April 13, 2018, that updated cost reporting instructions for freestanding hospice cost reports.[20] These instructions describe a number of new Level I edit conditions that required freestanding hospices to fill out certain parts of their cost reports. Specifically, section 4395 of this transmittal revised edit 1050A in the new Level I edits portion of ''Table 6—Edits'' to require that values entered into Worksheet A, column 7, lines 1, 2, 3, 4, 13, 28, 33, 37, and 38 must be greater than zero; and the sum of lines 14 and 42.50 must also be greater than zero. These Level I edits went into effect for freestanding hospice cost reports with a reporting period that ended on or after December 31, 2017.

Next, to remove outliers from this analysis, we applied another set of exclusions as described in the FY 2019 Hospice Wage Index and Payment Rate Update proposed rule (83 FR 20948). Specifically, we described how a trimming methodology is applied to cost reports so that statistical anomalies were minimized. For each calculated outcome (for example, average RHC costs per day), we excluded those values that are above the 99th percentile and those values that are below the 1st percentile. We refer to this trim as the ''1% Trim''. The data we exclude vary for each level of care. For example, we may exclude a hospice's data when calculating RHC costs per day, but not exclude it when calculating GIP costs per day. After all the described exclusions were applied, table 3 below shows how many freestanding cost reports were used for this analysis.

TABLE 3—NUMBER OF FREESTANDING COST REPORTS AFTER THE LEVEL I EDITS EXCLUSION AND 1% TRIM

Level of care	Number of cost reports after exclusions	Number of days by level of care (FY 2017)
RHC	1,098	41,329,675
GIP	809	783,335
CHC	437	187,498
IRC	906	134,146

Note: We begin with the 3,207 freestanding cost reports that remained after applying exclusions in 1–3 (table 2). After applying the Level I edits, 1,120 freestanding cost reports remained. Not all cost reports contain information on each level of care. Numbers shown indicate the number of cost reports available for analysis for each level of care after all exclusions, including the 1% trim are applied.

Primarily, due to the small sample size of provider-based hospices after these exclusions (see explanation below), we ultimately decided to only use freestanding hospice cost reports. As shown in table 2, there were 918 provider-based cost reports (that is, 26 SNF, 473 HHA, and 419 hospital) before applying the new Level I edits to the provider-based hospice cost reports. After applying the new Level I edits there were 96 provider-based cost reports remaining. Likewise, in MedPAC's March 2017 Report to Congress, they stated that included in the costs of provider-based hospices are overhead costs allocated from the parent provider, which contribute to provider-based hospices having higher costs than freestanding hospices. The Commission believes payment policy should focus on the efficient delivery of services to Medicare beneficiaries. If freestanding hospices are able to provide high-quality care at a lower cost than provider-based hospices, payment rates should be set accordingly, and the higher costs of provider-based hospices should not be a reason for increasing Medicare payment rates.[21] Industry representatives also suggested various edits to improve the quality of data submitted on the cost report before being accepted by the Medicare Administrative Contractors (MACs) (83 FR 20949).

However, we did consider using both freestanding and provider-based cost reports, with all cost report adjustments, including Level I edits, to rebase the payment rates for CHC, IRC, and GIP. We also considered not applying the Level I edits to the freestanding cost reports for this rebasing analysis. Both of these alternative approaches are described in section V.E. of this proposed rule. The remaining discussion in this section will focus on our analysis of freestanding hospice cost reports for FY 2017. This analysis focused on the costs per day by level of care found within the hospice cost reports and reported on Worksheet C, column 3, Lines 3, 8, 13 and 18.

b. Hospice Claims Data

We created an analytic data set based on Medicare hospice claims downloaded from the Chronic Condition Data Warehouse—Virtual Research Data Center (CCW VRDC) to examine hospice utilization on specific days during FY 2017. We assigned a wage index (using the FY 2017 hospice wage indices) to each day of hospice service based on the core-based

[19] FY 2017 cost reports had a start date on or after October 1, 2016 and before October 1, 2017.

[20] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3P243.pdf.*

[21] Medicare Payment Advisory Commission (MedPAC). ''Hospice Services.'' *Report to the Congress: Medicare Payment Policy.* Washington, DC. March 2018. P. 341. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch12_sec.pdf?sfvrsn=0.*

statistical area (CBSA) where a particular day's hospice services took place.[22] We merged information from the June 2018 release of the CMS POS file to identify characteristics of the hospice including: Ownership type, census division (based on the hospice's state), and whether the hospice's main office was located either in an urban or rural location. This data was used in the subsequent section in calculating costs per day by level of care.

c. Calculating Costs per Day by Level of Care

In order to compute the average cost per day for each level of care using information from the freestanding hospice cost reports, after applying the exclusions, we made several adjustments to the average cost calculations, as described below.

Costs reported on Medicare cost reports vary due to many factors, including variation in costs driven by geographic location. For example, all else equal, hospices in high wage areas (for example, New York City) may have higher costs compared to hospices in low wage areas. Daily payment rates for hospice are adjusted to account for geographic differences in wage rates. However, this geographic wage adjustment is only applied to the labor share of the base payment rate. The labor share for RHC and CHC is 68.71 percent, for GIP it is 64.01 percent and for IRC, it is 54.13 percent. Medicare adjusts for these wage differences by first multiplying the base payment rate paid to hospices by the labor share of the base payment rate. That value is then multiplied by the wage index assigned to the CBSA where the hospice provided services to the patient. Therefore, it is important to calculate average costs after removing any regional differences that may be driven by wages, otherwise we would over-adjust for wage differences across regions. For example, we remove the wage differences in RHC costs by calculating the following value for each hospice:

Adjusted RHC cost per day = RHC cost per day from 2017 cost reports * (0.6871) /

Hospice's average wage index for all RHC days in FY 2017 +

RHC cost per day from 2017 cost reports * (1 - 0.6871)

Note: 0.6871 is the labor share used to wage index adjust RHC payments

We perform a similar calculation for the other levels of care using the corresponding cost per day from FY 2017 cost reports and the appropriate labor share for CHC, IRC, and GIP. For example, the adjusted GIP cost per day uses the same formula, but instead includes GIP cost per day from FY 2017 cost reports, the hospice's average wage index for all GIP days in the formula, and the GIP labor share of 64.01 percent.

Due to exclusions mentioned previously, not all hospices that submitted claims during FY 2017 have a corresponding cost report in our final sample. As a result, the characteristics of the sample of cost reports used to calculate average cost per day for each level of care do not necessarily match up with the characteristics of all hospices that submitted claims during FY 2017. If not accounted for, our sample of cost reports may over-represent certain types of hospices. To correct for this, we categorize each hospice in our sample by facility type,[23] ownership type,[24] urban/rural status,[25] and size.[26] For each category of hospices and the calculations for each level of care, we use the following steps:

1. Using claims, we compute the total number of days provided in FY 2017 by all hospices within a particular category;

2. We compute the total number of days, as reported on the claims provided in FY 2017, using only the hospices in our trimmed sample of cost reports within a particular category (Table 3); and

3. For each level of care and each category of hospices, we construct a ratio using the value in Step 1 over the value in Step 2.

For each cost report in our sample, we multiply each provider's days (as reported on claims) by level of care by the ratio in order to make the sample cost reports more representative of the overall population of hospices. We then multiply the provider's average per diem cost as reported on the cost report times the number of adjusted days from the prior step to yield total costs by level of care for that provider. We then compute the weighted average for each level of care by summing across hospices the total costs by level of care divided by the sum of the adjusted days across the cost reports in our sample.[27]

$$\text{Weighted Average IRC Cost Per Day} = \frac{\sum_{i=1}^{n} \text{Cost}_i * \text{Number of Days}_i}{\sum_{i=1}^{n} \text{Number of Days}_i}$$

Note: Where Cost_i represents the IRC cost per day reported by hospice i and Number of Days_i represents the number of IRC days provided by hospice *i* as found in FY 2017 hospice claims and adjusted upward by the ratio described above.

[22] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index/FY-2017-Final-Hospice-Wage-Index.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending*

[23] Freestanding versus provider-based.

[24] We only divide the freestanding cost reports into ownership type categories. We use the ownership type categories from the POS: For-profit, government, non-profit, and other. Due to limited sample size we do not break out the provider-based hospices into ownership type.

[25] Urban/rural status is reported on the POS and corresponds to the mailing address of the hospice.

[26] We divide hospices into three categories based on their number of RHC days in FY 2017: Large (>=20,000 RHC days), medium (3,500–19,999 RHC days), and small (0–3,499 RHC days).

[27] The formula describes the average cost per day calculation for IRC, however, the same formula can be adapted for each level of care.

We compute the weighted average equation for each level of care. For example, we use a separate equation to calculate the average GIP cost per day that uses GIP costs and GIP days. The equation as described above is an approach to calculate the average per day cost for each level of care. However, Medicare pays for the CHC level of care using a per hour rate instead of a per day rate. We calculated each hospice's hourly cost of CHC by taking their CHC cost per day from the hospice cost report and dividing it by their average number of hours of CHC provided on CHC days occurring in FY 2017 as reported on each hospice's claims. Each hospice's CHC cost per hour (adjusted by average number of hours of CHC) is then averaged (using the weighted average formula discussed above) across all hospices in our sample to create the overall average of CHC cost per hour. To convert the CHC cost per hour into a CHC cost per day we multiply the average CHC cost per hour by 24 hours. It is important to note that each hospice's hourly CHC cost is based on their average number of CHC minutes per day, which is less than 24 hours. That means a full CHC per day payment (which covers 24 hours) will be larger than the average CHC cost per day (which covers a time period less than 24 hours).

Applying all of the steps as described above, average costs per day by level of care in FY 2017 are listed in Table 4 below:

TABLE 4—AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017

Level of care	Average cost per day
RHC	$130.83
CHC (24 Hours)[28]	1,307.76
CHC (Per Hour)	54.49
IRC	438.98
GIP	953.96

The current payment system pays hospices a two-tiered rate for RHC. RHC days during the first 60 days are paid a higher per diem rate compared to any RHC days after day 60. Hospices do not report RHC costs separately for the first 60 days versus RHC days after day 60. However, we can estimate the RHC costs in the first 60 days versus after 60 days by making the same assumption that was made to calculate the two-tiered payment. That is, in the FY 2016 hospice final rule (80 FR 47166), we calculated resource use ratios to determine the differences in resource utilization for the first 60 days and any RHC days after day 60. For the creation of the two-tiered RHC rate (80 FR 47166), the following ratios were used:

- Days 1 through 60: The ratio of average resource use for RHC days in days 1 through 60 to average resource use across all RHC days was 1.2603 to 1.
- Days 61 and beyond: The ratio of average resource use for RHC days after day 60 to the average resource use across all RHC days was 0.8722 to 1.

We multiplied the average cost per day for RHC in FY 2017 by the corresponding resource use ratio to calculate the average cost per day for the first 60 days and any RHC days after 60 days. The resulting average cost per day for RHC is shown in Table 5.

TABLE 5—AVERAGE RHC COSTS (FY 2017) PER DAY FOR DAYS 1 THROUGH 60 AND DAYS 61+

RHC level of care	Average cost per day	Resource use ratio	Average cost per day in FY 2017 (based on days of RHC)
Days 1–60	$130.83	1.2603	$164.89
Days 61+	130.83	0.8722	114.11

To determine if there is any misalignment between the average costs of providing CHC, IRC and GIP and the per diem payment rates for these levels of care, we inflated the average costs in FY 2017 to FY 2019 dollars. We did this by multiplying the average FY 2017 costs by level of care by the hospice market basket update payment update for FY 2018 (82 FR 36649) and FY 2019 (83 FR 38630) less the multifactor productivity adjustments (MFP). Table 6 below shows the estimated average costs for CHC, IRC and GIP for FY 2019 (that is, taking the average FY 2017 cost per day by each level of care inflated to 2019 dollars).

TABLE 6—ESTIMATED AVERAGE COSTS (FY 2019) FOR CHC, IRC AND GIP

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
CHC (per Hour)	$54.49	× 1.021	× 1.021	$56.80
IRC	438.98	× 1.021	× 1.021	457.61
GIP	953.96	× 1.021	× 1.021	994.45

We also analyzed the average costs of the RHC for the first 60 days and any RHC days after day 60 inflated from FY 2017 dollars to FY 2019 dollars by applying the hospice market basket update less the MFP adjustments. The results in Table 7 show the estimated average costs for RHC by days for FY 2019.

[28] Based off a full CHC per day payment (which covers 24 hours).

TABLE 7—ESTIMATED AVERAGE COSTS FOR RHC (FY 2019) DAYS 1 THROUGH 60 AND DAYS 61+

Level of care	FY 2017 average costs	FY 2018 hospice market basket update less productivity adjustment	FY 2019 hospice market basket update less productivity adjustment	FY 2019 estimated average costs
RHC Days 1–60	$164.89	× 1.021	× 1.021	$171.89
RHC Days 61+	114.11	× 1.021	× 1.021	118.95

We then compared the FY 2019 average costs for CHC, IRC and GIP to the FY 2019 payment rates for these three levels of care. Our analysis shows that there is a misalignment between average costs and payment for these three levels of care. Table 8 below shows: The percent of total hospice days by level of care; the estimated average FY 2019 costs by level of care; the current FY 2019 per diem payment rates; and the estimated percent increase to the payment rates to more accurately align the per diem payments for CHC, IRC and GIP with the costs of providing these levels of care.

TABLE 8—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENTS FOR CHC, IRC AND GIP

Level of care	Percent of days by level of care in FY 2018 *	Estimated FY 2019 average costs per day	FY 2019 per diem payment rates	Estimated percent payment increase needed to align with costs
CHC	0.2	$1,363.26/$56.80 (per hour) [29] ..	$997.38/$41.56 (per hour)	+36.6
IRC	0.3	$457.61	$176.01	+160.0
GIP	1.3	$994.45	$758.07	+31.2

* RHC days accounted for 98.2 percent of all hospice days in FY 2018.

The payment rates for CHC, IRC, and GIP are significantly less than the average costs of providing care. We also compared the FY 2019 average costs for RHC for the first 60 days and any RHC days after day 60 to the FY 2019 payment rates for RHC and the percentage difference between payment and average costs and the results are shown in Table 9 below.

TABLE 9—COMPARISON OF FY 2019 AVERAGE COSTS TO PAYMENT FOR RHC

Level of care	Estimated FY 2019 average costs per day	FY 2019 payment rates	Percent difference between payment and costs
RHC Days 1–60	$171.89	$196.25	+14.2
RHC Days 61+	118.95	154.21	+29.6

For RHC, the payment rates significantly exceed the average costs of providing care for this level of care for the first 60 days and any RHC days after day 60.

3. Proposed Rebasing of the CHC, IRC, and GIP Payment Rates for FY 2020

As mentioned above, section 1814(i)(1)(A) of the Act requires that payment for hospice services must be an amount equal to the costs which are reasonable and related to the cost of providing hospice care. As described above, the average costs of providing CHC, IRC and GIP are significantly higher than the payment amounts for these three levels of care. Using the hospice payment reform authority under section 1814(i)(6) of the Act, we are proposing to rebase the payment rates for CHC, IRC, and GIP by setting these payment amounts equal to the FY 2019 estimated average costs per day, as described in the methodology above, before application of the hospice payment update percentage outlined in section III.C of this proposed rule. We are proposing to rebase the payment rates for CHC, IRC, and GIP as follows:

TABLE 10—PROPOSED REBASED PAYMENT RATES FOR CHC, IRC, AND GIP *

Level of care	Proposed rebased payment rates *
Continuous Home Care (CHC).	$56.80 per hour/ $1,363.26 (per day).[30]
Inpatient Respite Care (IRC).	$435.82.**
General Inpatient Care (GIP).	$994.45.

* Prior to application of the hospice payment update percentage of 2.7 percent outlined in section III.B of this proposed rule.

** IRC payment rate accounts for 5 percent coinsurance ($457.61/1.05 = $435.82).

Although there is no coinsurance amount for RHC, CHC or GIP, the

[29] Based off a full CHC per day payment (which covers 24 hours).

[30] Based off a full CHC per day payment (which covers 24 hours).

amount of coinsurance for each respite care day is equal to 5 percent of the payment made by Medicare for a respite care day. Section 1813(a)(4)(A)(ii) of the Act states that the amount payable for hospice care shall be reduced in the case of respite care provided by (or under arrangements made by) the hospice program, by a coinsurance amount equal to 5 percent of the amount estimated by the hospice program (in accordance with regulations of the Secretary) to be equal to the amount of payment under section 1814(i) to that program for respite care. To ensure payments (both paid by Medicare and collected from the beneficiary via coinsurance) under a rebased IRC rate equal the average per-diem cost of IRC, we set the rebased IRC payment rate equal to the average per-diem cost of IRC divided by 1.05. The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began. The individual hospice coinsurance period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

Section 1814(i)(6)(D)(ii) of the Act requires that any revisions to the methodology for determining the payment rates for other services included in hospice care to be done in a budget-neutral manner in the fiscal year in which such revisions in payment are implemented as would have been made for care in the fiscal year if such revisions had not been implemented. Therefore, in order to offset the proposed increases in payment rates to the CHC, IRC, and GIP levels of care, we are proposing to reduce the RHC payment rates by 2.71 percent in order to implement rebasing in a budget-neutral manner in FY 2020. Reducing the RHC payment rate to a level equal to the estimated RHC costs would require a reduction in the RHC payment rate that exceeds the proposed 2.71 percent. While we are rebasing the per diem payment rates for CHC, GIP, and IRC to more accurately align the payment with costs, the reduction to the RHC payment rates is not considered rebasing as the 2.71 percent reduction does not bring the RHC payment in alignment with the costs of providing this level of care. The purpose of the 2.71 percent reduction to the RHC payment rates is to ensure that the revisions to the payment rates for CHC, GIP and IRC are made in a budget-neutral manner, in accordance with the law.

To calculate the proposed 2.71 percent reduction to the RHC payment rates, we first calculate two sets of payments using different payment parameters.

1. Total payments for hospice days provided during FY 2018 under the existing FY 2019 payment rates and FY 2019 wage indices.[31]

2. Total payments for hospice days provided during FY 2018 under a new RHC payment rate and the rebased payment rates for CHC, IRC, and GIP.

We set the RHC payment rate in step (2) equal to the value that makes total payments between step (1) and step (2) equivalent. We calculate that rate using the following steps:

1. We calculate the difference in Medicare payments when using the rebased CHC, IRC, and GIP payment rates instead of the payment rates in place during FY 2019.

2. We calculate one minus the value from Step (1) over the RHC payments made under the payment rates in place during FY 2019.[32]

3. We multiply the value in Step (2) by each RHC payment rate (the first 60 days and any RHC days after day 60) in place during FY 2019 to establish the budget- neutral RHC payment rates (the first 60 days and any RHC days after day 60).

The calculated payment rates in Step (3) will make the total payments made under the rebased FY 2019 payment rates equal to the total payments made under the existing FY 2019 payment rates.

The results of this calculation demonstrate that in order to rebase CHC, IRC, and GIP levels of care in a budget-neutral manner, the RHC payment rates would need to be reduced by 2.71 percent. The proposed 2.71 percent reduction would be applied to the RHC payment rates for the first 60 days and RHC days after day 60 (that is we would take each of the RHC payment rates and multiply by the 0.9729 to determine the FY 2019 RHC payment rates).

To summarize, we are proposing: To rebase the payment rates for CHC and GIP and set these rates equal to their estimated FY 2019 average costs per day (see Table 10 above); we are proposing to rebase the payment rate for IRC and set this rate equal to the estimated FY 2019 average cost per day, with a reduction of 5 percent to the estimated FY 2019 average cost per day to account for coinsurance (see Table 10 above); and we are proposing a 2.71 percent reduction to the RHC payment rates to offset the proposed increases to the CHC, IRC, and GIP payment rates as the proposed increases in the payment rates for these three levels of care must be implemented in a budget-neutral manner in accordance with section 1814(i)(6)(D)(ii) of the Act. While the per diem payments were a reasonable way to pay hospices, we think the proposal to rebase the per diem payments for CHC, GIP, and IRC better reflects the costs of providing care. This proposal is in accordance with section 1814(i)(A) of the Act that provides the authority to set such payments reasonable to the cost of providing hospice care.

It is our intent to ensure that payment rates under the hospice benefit align as closely as possible with the average costs hospices incur when efficiently providing covered services to beneficiaries. This proposal is not intended to place an arbitrary limit on hospice services and we believe the rebased rates for CHC, IRC, and GIP may help appropriately increase access to these levels of care. We continue to expect hospices to adhere to the long-standing policy to provide ''virtually all'' care during a hospice election as articulated in the 1983 Hospice Care proposed and final rules as well as most recently in FY 2019 Hospice Wage Index and Payment Rate Update final rule. We also believe this proposal is responsive to industry concerns regarding the challenges in securing needed contracts with facilities to provide inpatient levels of care by more accurately aligning Medicare payments for hospice services for higher cost levels of care. We are soliciting comments on our proposal to rebase the payment rates for CHC, IRC, and GIP, which results in an increase in the payment rates to those three levels of care, and to maintain overall budget neutrality through a proposed reduction to the RHC payment rates.

We believe that rebasing the per diem payment amounts for CHC, GIP, and IRC is appropriate in order to better align payments with the costs of providing care and that potential, subsequent increases in utilization of those levels of care would not necessarily be inappropriate. However, we are also soliciting comment on whether rebasing the payment amounts for CHC, GIP, and

[31] FY 2018 is the most, current full year of data available.

[32] Using the average per-diem costs generated from our sample of freestanding hospice cost reports, rebasing CHC, IRC, and GIP results in extra payments of $465,983,031.15 for those levels of care. The RHC payments that were made under the payment rates in place during FY 2019 were $17,218,209,794.15. One minus the value of the extra payments over the RHC payments equals 0.9729.

IRC could create an adverse incentive for providers to inappropriately steer patients to a higher, more specialized level of care when that level of care is not medically indicated.

B. Proposed FY 2020 Hospice Wage Index and Rate Update

1. Proposed Wage Index Lag Elimination

Historically we have calculated the hospice wage index values by using the prior fiscal year's pre-floor, pre-reclassified hospital wage index. In an effort to align with the Inpatient Prospective Payment System (IPPS) and other payment systems, we are proposing to change the hospice wage index methodology. Specifically, we are proposing to change from our established policy of using the pre-floor, pre-reclassified acute care hospital wage index from the prior fiscal year as the basis for the hospice wage index, and instead to align with the same timeframe used by the IPPS and other payment systems. In other words, we are proposing to use the pre-floor, pre-reclassified hospital wage index from the current fiscal year as the basis for the hospice wage index. Under this proposal, the FY 2020 hospice wage index would be based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

Using the concurrent pre-floor, pre-reclassified hospital wage index would result in the most up-to-date wage data being the basis for the hospice wage index, increasing payment accuracy. It would also result in more consistency and parity in the wage index methodology used by Medicare. Medicare's skilled nursing facility (SNF), home health and acute care hospital prospective payment systems already use the most current wage index data as the basis for their wage indices. Thus, if our proposal is finalized, the wage-adjusted Medicare payments of various provider types would be based upon wage index data from the same timeframe. We are considering similar policies to use the concurrent pre-floor, pre-reclassified hospital wage index data in other Medicare payment systems, such as inpatient psychiatric facilities and inpatient rehabilitation facilities.

Overall, the impact between the FY 2020 wage index with the 1-year lag and the proposed FY 2020 wage index removing the 1-year lag is 0.0 percent due to the wage index standardization factor, which ensures that wage index updates and revisions are implemented in a budget-neutral manner. The anticipated impact on Medicare hospice payments due to the change in the wage index methodology can be found in table 11 below.

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Table 11: Estimated Impact on Medicare Hospice Payments, FY 2020 Hospice Wage Index with and without 1-Year Lag

	Hospices	FY 2020 Wage Index with 1-year Lag Minus FY 2019 Wage Index *(Percentage Change)*	FY 2020 Wage Index without 1-Year Lag Minus FY 2020 Wage Index with 1-Year Lag *(Percentage Change)*
All Hospices	4,569	0.0%	0.0%
Hospice Type and Control			
Freestanding/Non-Profit	601	-0.1%	0.1%
Freestanding/For-Profit	2,819	0.1%	-0.1%
Freestanding/Government	39	0.1%	-0.3%
Freestanding/Other	322	-0.2%	0.1%
Provider/HHA Based/Non-Profit	396	-0.3%	0.0%
Provider/HHA Based/For-Profit	194	-0.2%	0.0%
Provider/HHA Based/Government	101	-0.3%	0.2%
Provider/HHA Based/Other	97	-0.1%	0.0%
Subtotal: Freestanding Provider Type	3,781	0.0%	0.0%
Subtotal: Provider/HHA Based Provider Type	788	-0.3%	0.0%
Subtotal: Non-Profit	997	-0.1%	0.1%
Subtotal: For Profit	3,013	0.1%	-0.1%
Subtotal: Government	140	0.0%	-0.1%
Subtotal: Other	419	-0.2%	0.1%
Hospice Type and Control: Rural			
Freestanding/Non-Profit	154	0.0%	0.5%
Freestanding/For-Profit	328	0.1%	0.2%
Freestanding/Government	20	-0.3%	0.0%
Freestanding/Other	45	-0.2%	0.2%
Provider/HHA Based/Non-Profit	157	-0.4%	0.0%
Provider/HHA Based/For-Profit	47	0.0%	0.1%
Provider/HHA Based/Government	74	0.0%	0.3%
Provider/HHA Based/Other	54	-0.8%	0.5%
Hospice Type and Control: Urban			
Freestanding/Non-Profit	447	-0.1%	0.1%
Freestanding/For-Profit	2,491	0.1%	-0.1%
Freestanding/Government	19	0.2%	-0.3%
Freestanding/Other	277	-0.2%	0.1%
Provider/HHA Based/Non-Profit	239	-0.3%	0.0%
Provider/HHA Based/For-Profit	147	-0.3%	0.0%
Provider/HHA Based/Government	27	-0.5%	0.1%
Provider/HHA Based/Other	43	0.1%	-0.1%

Hospice Location: Urban or Rural			
Rural	879	-0.1%	0.2%
Urban	3,690	0.0%	0.0%
Hospice Location: Region of the Country (Census Division)			
New England	157	-0.5%	-0.5%
Middle Atlantic	281	-0.2%	-0.1%
South Atlantic	554	-0.1%	0.0%
East North Central	543	-0.4%	0.0%
East South Central	263	-0.2%	0.1%
West North Central	404	-0.3%	0.6%
West South Central	875	0.3%	0.1%
Mountain	458	-0.5%	0.2%
Pacific	988	0.9%	-0.2%
Outlying	46	-1.3%	-0.3%
Hospice Size			
0 - 3,499 RHC Days (Small)	971	0.5%	0.0%
3,500-19,999 RHC Days (Medium)	2,130	0.1%	0.0%
20,000+ RHC Days (Large)	1,468	0.0%	0.0%

Note: 3 hospices with claims in FY 2018 were dropped from the analysis because they had no information on their location, facility type, or ownership status in the December 2018 POS file.
Source: FY 2018 hospice claims data as of December 31, 2018 from the CCW Research Identifiable Files (RIFs), accessed January 2019.

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We invite comments on this proposal to align the hospice wage index with that of the SNF PPS and Home Health PPS, by using the most current pre-floor, pre-reclassified IPPS hospital wage index as the basis for the hospice wage index.

2. Proposed FY 2020 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospice agencies under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

In section III.B.1 above, we proposed to use the current FY's hospital wage index data to calculate the hospice wage index values. For FY 2020, the proposed hospice wage index would be based on the FY 2020 hospital pre-floor, pre-reclassified wage index. This means that the hospital wage data used for the hospice wage index are not adjusted to take into account any geographic reclassification of hospitals including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The appropriate wage index value is applied to the labor portion of the hospice payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or IRC.

In the FY 2006 Hospice Wage Index final rule (70 FR 45135), we adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the Core-Based Statistical Areas (CBSAs) within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas. For FY 2020, there are two CBSAs without a hospital from which hospital wage data can be derived: 25980, Hinesville-Fort Stewart, Georgia and 16180, Carson City, NV. The FY 2020 wage index value for Carson City, NV is 1.0518 and the wage index value for Hinesville-Fort Stewart, Georgia is 0.8237.

There exist some geographic areas where there were no hospitals, and thus, no hospital wage data on which to base the calculation of the hospice wage index. In the FY 2008 Hospice Wage Index final rule (72 FR 50217 through 50218), we implemented a methodology to update the hospice wage index for rural areas without hospital wage data. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs, to represent a reasonable proxy for the rural area. The term ''contiguous'' means sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For

FY 2020, we propose to continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047, subsequently adjusted by the hospice floor.

As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are subject to application of the hospice floor to compute the hospice wage index used to determine payments to hospices. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor, pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15 which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

The proposed hospice wage index applicable for FY 2020 (October 1, 2019 through September 30, 2020) is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html.*

3. Wage Index Comment Solicitation

As we stated above, historically, we have calculated the hospice wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the hospice wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust hospice payments and suggestions for possible updates and improvements to the geographic adjustment of hospice payments.

4. Proposed FY 2020 Hospice Payment Update Percentage

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the inpatient hospital market basket percentage increase set out under section 1886(b)(3)(B)(iii) of the Act, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the inpatient market basket percentage increase for that FY.

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

The proposed hospice payment update percentage for FY 2020 is based on the estimated inpatient hospital market basket update of 3.2 percent (based on IHS Global Inc.'s fourth-quarter 2018 forecast with historical data through the third quarter 2018). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the estimated inpatient hospital market basket update for FY 2020 of 3.2 percent must be reduced by a MFP adjustment as mandated by Affordable Care Act (currently estimated to be 0.5 percentage point for FY 2020). In effect, the proposed hospice payment update percentage for FY 2020 would be 2.7 percent.

Currently, the labor portion of the hospice payment rates is as follows: For RHC, 68.71 percent; for CHC, 68.71 percent; for General Inpatient Care, 64.01 percent; and for Respite Care, 54.13 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, the non-labor portion of the payment rates is as follows: For RHC, 31.29 percent; for CHC, 31.29 percent; for General Inpatient Care, 35.99 percent; and for Respite Care, 45.87 percent. Beginning with cost reporting periods starting on or after October 1, 2014, freestanding hospice providers are required to submit cost data using CMS Form 1984–14 (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospice-2014.html*). We continue to analyze this data for possible use in updating the labor portion of the hospice payment rates. Any changes to the labor portions would be proposed in future rulemaking and would be subject to public comments.

5. Proposed FY 2020 Rebased Hospice Payment Rates

There are four hospice payment categories, all of which are distinguished by the location and intensity of the services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and GIP is provided to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In addition, in that final rule, we implemented a Service Intensity Add-on (SIA) payment for RHC when direct patient care is provided by a RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours total) that occurred on the day of service, if certain criteria are met. In order to maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a SIA budget neutrality factor.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47177), we will continue to make the SIA payments budget neutral through an annual determination of the SIA budget neutrality factor (SBNF), which will then be applied to the RHC payment rates. The SBNF will be calculated for each FY using the most current and complete utilization data available at the time of rulemaking. For FY 2020, this calculation would also reflect the proposed increase in the hourly rate for CHC as a result of rebasing, discussed in section III.A.2.c of this proposed rule.

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments in order to eliminate the aggregate effect of annual variations in hospital wage data. In order to calculate the wage index

standardization factor, we simulate total payments using the proposed FY 2020 hospice wage index (no lag) and compare it to our simulation of total payments using the FY 2019 hospice wage index. By dividing payments for each level of care using the FY 2020 wage index (no lag) by payments for each level of care using the FY 2019 wage index, we obtain a wage index standardization factor for each level of care (the first 60 RHC days and RHC days after day 60 and, CHC, IRC, and GIP). The wage index standardization factors for each level of care are shown in the tables 12 and 13 below.

As discussed in section III.A.3 of this proposed rule, we are proposing to rebase the per diem payment rates for the CHC, IRC, and GIP levels of care. Section 1814(i)(6) of the Act, as amended by section 3132(a)(1)(B) of the Affordable Care Act, authorizes the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and for other purposes. The data collected may be used to revise the methodology for determining the payment rates for RHC and other hospice services (in a budget-neutral manner in the first year), no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. As mentioned above and outlined in the Affordable Care Act, hospice payment reform must be done in a budget-neutral manner. In other words, total estimated hospice expenditures under these rebased payment rates must equal total estimated hospice expenditures absent rebasing (we are assuming no change in utilization). In order to rebase the per diem payment amounts for CHC, IRC, and GIP in a budget-neutral manner, in section III.A.2.c we proposed that increases to the CHC, IRC, and GIP per diem payment amounts would be offset by corresponding decreases to the RHC per diem payment amounts to maintain overall budget neutrality.

The proposed FY 2020 payment rates for RHC would be the proposed FY 2019 payment rates, reduced by a budget neutrality factor as a result of the proposed rebasing of the CHC, IRC, and GIP payment amounts, adjusted by the SIA budget neutrality factor, adjusted by the wage index standardization factor, and increased by the 2.7 hospice payment update percentage as shown in table 12. The proposed FY 2020 rebased payment rates for CHC, IRC, and GIP would be the proposed rebased FY 2019 payment rates, adjusted by the wage index standardization factor and increased by the 2.7 market basket update percent as shown in table 13.

TABLE 12—PROPOSED FY 2020 HOSPICE RHC PAYMENT RATES

Code	Description	Proposed FY 2019 budget-neutral RHC payment rates *	SIA budget neutrality factor	Wage index standardization factor **	Proposed FY 2020 hospice payment update	Proposed FY 2020 payment rates
651	Routine Home Care (days 1–60)	$190.93	× 0.9924	× 1.0054	× 1.027	$195.65
651	Routine Home Care (days 61+)	150.03	× 0.9982	× 1.0054	× 1.027	154.63

* FY 2019 RHC payment rate for days 1–60: = $196.25 * 0.9729 = $190.93. FY 2019 RHC payment rate for days 61+ = $154.21 * 0.9729 = $150.03.

** Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

TABLE 13—PROPOSED FY 2020 HOSPICE CHC, IRC, AND GIP PAYMENT RATES

Code	Description	Proposed FY 2019 rebased payment rates	Wage index standardization factor *	Proposed FY 2020 hospice payment update	Proposed FY 2020 payment rates
652	Continuous Home Care Full Rate = 24 hours of care ($56.80 = hourly rate).	$1,363.26	× 1.0041	× 1.027	$1,405.81
655	Inpatient Respite Care	435.82	× 1.0049	× 1.027	449.78
656	General Inpatient Care	994.45	× 1.0060	× 1.027	1,027.43

* Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

Sections 1814(i)(5)(A) through (C) of the Act require that hospices submit quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index final rule (76 FR 47320 through 47324), we implemented a Hospice Quality Reporting Program as required by section 3004 of the Affordable Care Act. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. The proposed FY 2020 rates for hospices that do not submit the required quality data would be updated by the proposed FY 2020 hospice payment update percentage of 2.7 percent minus 2 percentage points. These rates are shown in tables 14 and 15.

TABLE 14—PROPOSED FY 2020 HOSPICE RHC PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	Proposed FY 2019 budget-neutral RHC payment rates *	SIA budget neutrality factor	Wage index standardization factor **	Proposed FY 2020 hospice payment update of 2.7% minus 2 percentage points = +0.7%	Proposed FY 2020 payment rates
651	Routine Home Care (days 1–60)	$190.93	× 0.9924	× 1.0054	× 1.007	$191.84
651	Routine Home Care (days 61+)	150.03	× 0.9982	× 1.0054	× 1.007	151.62

* FY 2019 RHC payment rate for days 1–60 = $196.25 * 0.9729 = $190.93. FY 2019 RHC rate for days 61+ = $154.21 * 0.9729 = $150.03.
** Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

TABLE 15—PROPOSED FY 2020 HOSPICE CHC, IRC, AND GIP PAYMENT RATES FOR HOSPICES THAT *DO NOT* SUBMIT THE REQUIRED QUALITY DATA

Code	Description	Proposed FY 2019 rebased payment rates	Wage index standardization factor *	Proposed FY 2020 hospice payment update of 2.7% minus 2 percentage points = +0.7%	Proposed FY 2020 payment rates
652	Continuous Home Care Full Rate = 24 hours of care ($56.80 = hourly rate).	$1,363.26	× 1.0041	× 1.007	$1,378.43
655	Inpatient Respite Care	435.82	× 1.0049	× 1.007	441.02
656	General Inpatient Care	994.45	× 1.0060	× 1.007	1,007.42

* Transition from FY 2019 Wage Index to FY 2020 Wage Index without 1-Year Lag.

6. Proposed Hospice Cap Amount for FY 2020

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47183), we implemented changes mandated by the IMPACT Act of 2014 (Pub. L. 113–185). Specifically, for accounting years that end after September 30, 2016, and before October 1, 2025, the hospice cap is updated by the hospice payment update percentage rather than using the CPI–U. The proposed hospice cap amount for the FY 2020 cap year will be $29,993.99, which is equal to the FY 2019 cap amount ($29,205.44) updated by the proposed FY 2020 hospice payment update percentage of 2.7 percent.

C. Proposed Election Statement Content Modifications and Proposed Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

1. Background

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of an individual may necessitate a transition from curative to palliative care if the individual so chooses. Medicare hospice care services are virtually all-inclusive, and are focused on meeting the physical, emotional, psychosocial and spiritual needs of the terminally ill individual and his or her family. In order to make an informed choice about whether to receive hospice care, the patient, family, and caregiver must have an understanding of what services are going to be provided by the hospice and that, because there is no longer a reasonable expectation for a cure, care should now focus on comfort and quality of life. The services covered under the Medicare hospice benefit are comprehensive such that, upon election, the individual waives all rights to Medicare payment for services related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made, except when provided by the designated hospice or attending physician. Because of the significance of this decision, the terminally ill individual must elect hospice care in order to receive services under the Medicare hospice benefit. Since we first implemented the Medicare hospice benefit in 1983, it has been our general view that the waiver required by law requires hospices to provide virtually all the care that is needed by terminally ill patients (48 FR 56010).

2. Current Statutory and Regulatory Requirements for Care Planning and Patient Rights

In order to be eligible to elect the Medicare hospice benefit, a beneficiary must be certified as terminally ill, meaning that the beneficiary has a medical prognosis of a life expectancy of 6 months or less if the illness runs its normal course (42 CFR 418.3). For the initial certification, the patient-designated attending physician (if any) and the hospice medical director (or hospice physician member of the interdisciplinary group (IDG)) must each certify in writing, at the beginning of the period, that the individual is terminally ill based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The regulations § 418.25 require that the hospice admit a patient only on the recommendation of the medical director in consultation with, or with input from, the patient's attending physician (if any).

In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider the principal diagnosis of the patient, all other health conditions, whether related or unrelated to the terminal condition, and all clinically relevant information

supporting all diagnoses. The clinical information and other documentation that support the medical prognosis must accompany the written certification and must be filed in the individuals' hospice medical record in accordance with the regulations at § 418.22(b)(2). Likewise, for the initial certification of terminal illness, the hospice CoPs at § 418.102(b) require that the hospice medical director (or hospice physician designee) consider not only the principal diagnosis and related conditions, but also current signs and symptoms affecting the patient, current medications and treatment interventions, and the medical management of unrelated conditions. Therefore, even prior to a patient's admission to hospice, the hospice medical director (or hospice physician designee) plays a pivotal role in making clinical determinations regarding related and unrelated conditions of terminally ill individuals. Once a beneficiary is certified as terminally ill, he or she becomes eligible to elect hospice care under the Medicare hospice benefit.

Because the receipt of hospice services under the Medicare hospice benefit is dependent upon the eligible beneficiary electing to receive hospice care, the regulations at § 418.24 provide the requirements of the hospice election statement. The election statement must include the identification of the designated hospice and attending physician (if any); the individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care; and the individual's or representative's acknowledgement that the individual waives the right to Medicare payment for services related to the terminal illness and related conditions, except when provided by the designated hospice or attending physician. Services unrelated to the terminal illness and related conditions remain eligible for Medicare coverage and payment outside of the hospice benefit.

Once the beneficiary has elected hospice care, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with a spoken and written notice of the patient's rights and responsibilities as required by the CoPs at § 418.52. Our rules state that the beneficiary has the right to be involved in developing his or her hospice plan of care; receive information about the services covered under the hospice benefit; and receive information about the scope of services that the hospice will provide and specific limitations on those services. The hospice program must assure the patient that its staff will protect patients' rights and will involve patients in decisions about their care, treatment and services.[33] Likewise, the regulations at § 476.78 state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review. CMS identifies the core functions of the QIO Program as:

- Improving quality of care for beneficiaries;
- Protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and
- Protecting beneficiaries by expeditiously addressing individual complaints.

Changes to the QIO Program were made to ensure that Medicare beneficiary needs are better met by designating a special type of organization, a Medicare Beneficiary and Family—Centered Care—Quality Improvement Organization (BFCC–QIO), to address quality of care concerns and appeals. When Medicare beneficiaries have a complaint that is not related to the clinical quality of healthcare, they and their healthcare provider can agree to participate in a flexible, dialogue-based resolution process, called ''immediate advocacy,'' which is coordinated by the BFCC–QIO (§ 476.110).

The patient rights are provided to the beneficiary at the beginning of a hospice election. Likewise, the hospice CoPs at § 418.54 require that the hospice registered nurse must complete the initial assessment within 48 hours after the election of hospice care, unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours. The initial assessment is to gather critical information necessary to treat the patient/family's immediate care needs. The hospice IDG, in consultation with the individual's attending physician (if any), must complete a comprehensive assessment no later than 5 calendar days after the election of hospice care. Additionally, the hospice CoPs at § 418.54(c) provide the content requirements for the initial and comprehensive assessments used to identify patient, family, and caregiver needs for physical, emotional, psychosocial, and spiritual care. As part of the comprehensive assessment, the hospice is required to assess the patient for complications and risk factors, which can affect care planning. The needs identified in these assessments drive the development and revisions of an individualized written plan of care for each patient as required by the CoPs at § 418.56. Collectively, the IDG, in consultation with the patient's attending physician (if any), makes care plan decisions for each patient to ensure that each care plan is individualized to meet the unique needs of each hospice beneficiary. The plan of care also must reflect patient, family, and caregiver preferences, goals, and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions and the CoPs at § 418.56(c) detail the plan of care content requirements, including the following:

(1) Interventions to manage pain and symptoms.

(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs.

(3) Measurable outcomes anticipated from implementing and coordinating the plan of care.

(4) Drugs and treatment necessary to meet the needs of the patient.

(5) Medical supplies and appliances necessary to meet the needs of the patient.

(6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record. Furthermore, as a condition for payment, the services provided must be consistent with the plan of care (§ 418.200).

Though hospices are responsible for providing all services needed for palliation and management of the terminal illness and related conditions, the 2008 Hospice Conditions of Participation final rule (73 FR 32088, June 5, 2008) states that while needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility (73 FR 32114). If a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions,

[33] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf.*

the hospice is to document such needs and communicate and coordinate with those health care providers who are identified as caring for the unrelated needs, as set out at § 418.56(e)(5). In the 2008 final rule, we stressed that the intent of the plan of care requirements are to show a direct link between the needs identified in the comprehensive assessment and the plan of care developed by the hospice. This also means that even if the hospice identified other needs in the patient assessment that were unrelated to the terminal illness and related conditions, these needs could not simply be ignored by the hospice; rather, the hospice would have to communicate and coordinate with the non-hospice providers that would be managing those conditions (73 FR 32114).

To ensure comprehensive and coordinated care, at § 418.56(e) we require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions. We also require hospices to designate a registered nurse (RN) who is a member of the IDG to coordinate implementation of the comprehensive plan of care. The designated RN must assure that coordination of care and continuous assessment of patient, family, and caregiver needs occur among staff providing services to the patient, family, and caregiver so that all IDG members are kept informed of the patient/family's status.[34] The goal of a coordinated communication process and a designated nurse coordinator is to adequately ensure that each patient's hospice care is coordinated both within the hospice and with other health care providers.

3. Services Unrelated to the Terminal Illness and Related Conditions

As discussed in section III.C.2., the hospice medical director, the attending physician (if any), and the hospice IDG determine, for each patient, what items and services are related and unrelated to the palliation and management of the terminal illness and related conditions during the admission process, the initial and comprehensive assessments, and in the development of the hospice plan of care. To the extent that individuals receive services outside of the Medicare hospice benefit during a hospice election, Medicare coverage is determined by whether or not the services are for the treatment of a condition completely unrelated to the individual's terminal illness and related conditions (48 FR 38146, 38148, August 22, 1983). As such, it is our long-standing position that services unrelated to the terminal illness and related conditions should be exceptional, unusual and rare given the comprehensive nature of the services covered under the Medicare hospice benefit (48 FR 56008, 56010, December 16, 1983). The Medicare claims processing system has edits in place to prevent other non-hospice claims from being processed while a patient is under a hospice election. For claims unrelated to the terminal illness and related conditions to be processed for Medicare payment while a patient is under a hospice election, the non-hospice provider or supplier must use a modifier or condition code on the claim to indicate that the service billed is unrelated to the patient's terminal condition. This is to help ensure that payment is made from the appropriate Medicare trust fund, and that duplicate payments are avoided.

In accordance with the hospice CoPs at § 418.56(e)(5), and in alignment with continuity of care principles,[35] the ongoing sharing of information with other non-hospice healthcare providers and suppliers furnishing services unrelated to the terminal illness and related conditions is necessary to ensure coordination of services and to meet the patient, family, and caregiver needs. The coordination requirements include that the hospice must develop and maintain a system of communication and integration amongst all providers furnishing care to the terminally ill patient. This communication helps to minimize fragmented care and to improve quality of life. Part of that communication process is the clear identification of what the related and unrelated conditions are and who is responsible for providing reasonable and necessary services for those conditions. As is the preferred practice for care coordination and communication,[36] both hospice and non-hospice providers typically document these discussions, which then becomes part of the patient's medical record with each provider. Accordingly, all Medicare providers and suppliers must be able to provide medical documentation to support payment for services billed (sections 1833(e) and 1815(a) of the Act). For non-hospice providers or suppliers billing Medicare for services received by hospice beneficiaries unrelated to their terminal illness and related conditions, this includes being able to provide documentation from the hospice listing the conditions (and thus items, drugs, and services) the hospice determined to be unrelated and documented as such on the hospice plan of care.

While hospices are required by the CoPs to have a system of communication with non-hospice providers to furnish such information, we have heard anecdotally from non-hospice providers stating that they are unable to reach or do not receive return calls from the hospice to discuss the hospice beneficiary's coordination of services that the hospice has determined unrelated to his or her terminal illness and related condition(s). Likewise, we have also received anecdotal reports from hospices who state they were unaware that patients had received care from non-hospice providers. In these reports, the hospice would first learn of this outside care when non-hospice providers would contact the hospice seeking reimbursement. If this care was related to the terminal illness and related conditions and the hospice did not make arrangements for such care, the beneficiary would be liable for the costs of receiving that care. Additionally, if non-hospice providers bill Medicare for services that potentially should have been the coverage responsibility of hospice, Medicare could be making duplicative payments for care related to the terminal illness and related conditions.

The OIG released a report in June of 2012 identifying situations where Medicare may have been paying twice for prescription drugs for hospice beneficiaries. This report also suggests that Medicare hospice beneficiaries themselves could also be paying unnecessary co-payments or coinsurance for prescription drugs.[37] In addition to being liable for unnecessary co-payments or coinsurance, if beneficiaries fill prescriptions to treat conditions that are related to the terminal illness and related conditions without such fills being arranged for by the hospice, the patient would be liable for the entire cost of the prescription.

[34] *https://www.cms.gov/Regulations andGuidance/Guidance/Manuals/downloads/som107ap_hospice.pdf.*

[35] Uijena, A., Schersa, H., Schellevisb, F., van den Bosch, W. How unique is continuity of care? A review of continuity and related concepts. Family Practice 2012; 29:264–271 doi:10.1093/fampra/cmr104.

[36] National Quality Forum (NQF), Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination: A Consensus Report, Washington, DC: NQF; 2010.

[37] Office of the Inspector General, Department of Health and Human Services. Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice. June, 2012. A–06–10–00059. *https://oig.hhs.gov/oas/reports/region6/61000059.pdf.*

The OIG identified four common categories of prescription drugs that are typically used to treat end-of-life symptoms that were being covered under Part D for beneficiaries under a hospice election. These four categories of drugs included analgesics, anti-nauseants, laxatives, and antianxiety agents. As a result of this report, CMS issued the first of several memoranda seeking to clarify the criteria for determining payment responsibility under the Part A hospice benefit and Part D for drugs prescribed to hospice beneficiaries. Part D plan sponsors were encouraged to place beneficiary-level prior authorization (PA) requirements on drugs being processed through Part D for hospice beneficiaries. The purpose of this PA form is to facilitate coordination between Part D sponsors, hospices, and pharmacists. Two primary uses are to document that a drug is unrelated to a beneficiary's terminal prognosis and to convey a beneficiary's change in hospice status. It may also be used by hospice providers to communicate and update the medication list from the beneficiary's plan of care.[38] In 2014, when the PA was instituted for all beneficiaries enrolled in hospice, utilization was reduced for both drugs in and outside of the four categories. However, when the PA was lifted for drugs not in the four categories (that is, maintenance drugs) there have been steady increases in utilization of these drugs by hospice beneficiaries through Part D.[39] Recent analyses of Part D prescription drug event (PDE) data suggest that the current PA process has reduced Part D program payments for drugs in the four targeted categories and that utilization patterns are sensitive to the PA process.[40]

After a hospice election, many maintenance drugs or drugs used to treat or cure a condition are typically discontinued as the focus of care shifts to palliation and comfort measures. However, there are maintenance drugs that are appropriate to continue as they may offer symptom relief for the palliation and management of the terminal illness and related conditions. Some examples of maintenance drugs include those to manage conditions such as heart disease, COPD, and diabetes. We continue to receive complaints from Part D plan sponsors and pharmacies that some hospice providers fail to respond to frequent outreach efforts from Part D sponsors seeking recovery for claims in the four categories or to clarify payment responsibility for medications for hospice beneficiaries. We believe that this represents a lack of coordination between hospices and Part D pharmacies and sponsors, which ultimately affects the quality of care furnished to an especially vulnerable population and results in additional costs to beneficiaries, as well as Part D plan sponsors.

In previous years' hospice proposed rules, we have included data on non-hospice expenditures for beneficiaries under a hospice election. These total non-hospice expenditures include beneficiary cost-sharing amounts. For Parts A and B, the beneficiary cost-sharing amounts in FY 2017 totaled approximately $138 million and for Part D, the beneficiary cost-sharing totaled approximately $68.6 million (83 FR 20946 through 20947). We believe that this is a substantial financial burden being placed on terminally ill individuals for services that potentially should have been covered by hospice. In previous years' rules, we have provided data and case studies on the most frequently reported principal diagnoses on hospice claims and their associated non-hospice expenditures for what were determined to be services for unrelated conditions (80 FR 47154 and 81 FR 25510). These diagnoses included lung cancer, cerebral degeneration of the brain (that is, conditions that cause dementia), chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF). We also discussed the recommended evidence-based clinical practice guidelines for those diagnoses, including the use of certain types of DME, supplies and drugs. Our analysis revealed that items such as oxygen, respiratory agents, hospital beds, wheelchairs, common palliative drugs, and disease-specific drugs were not being furnished or covered by hospice even though we would expect such items to be clinically indicated and provided for the palliation and management of the terminal illness and related conditions (80 FR 47154). This suggests that hospice beneficiaries may be incurring unnecessary financial burden as they are having to seek out and pay for items and services for pain and symptom relief—services that hospice should be furnishing and covering.

We have received numerous anecdotal reports from beneficiaries, families, and non-hospice providers that hospice patients are obtaining needed drugs and other services outside of the hospice benefit because they have been told that hospice would not cover the drugs as the hospice determined that they were unrelated to the terminal illness and related conditions. Many of these anecdotal reports state that the beneficiaries and families believe that these items, services, and drugs were related to the terminal illness and related conditions and believed that they should have been provided by the hospice. The beneficiaries and/or the families stated that they did not know they would have to seek care outside of the hospice benefit for these conditions because the hospice did not tell them these items, services, and drugs would not be furnished by the hospice until the patient needed them. The Medicare Beneficiary Ombudsman Office also has received similar reports. The Medicare Ombudsman helps beneficiaries with Medicare-related complaints, grievances, and information requests, regarding what beneficiaries need to know to make appropriate health care decisions; beneficiary rights and protections under Medicare; and how to get issues resolved.[41] Whereas the Medicare Ombudsman helps with providing general information about Medicare and navigating through various Medicare processes to resolve issues, the BFCC–QIOs assist Medicare beneficiaries with specific quality of care complaints for people with Medicare to improve the effectiveness, efficiency, economy, and quality of services for people with Medicare. The BFCC–QIOs provide services to help Medicare beneficiaries file appeals if they think their coverage is ending too soon; to conduct quality of care and medical necessity reviews, and; to help with grievances. Both entities are in place to make sure beneficiary rights are protected.

The Medicare Ombudsman also shares information with the Secretary of Health and Human Services, Congress, and other organizations about what does and doesn't work well to improve the quality of the services and care beneficiaries get through Medicare. Examples of recent Medicare Ombudsman reports of patients being told only after electing the benefit and the commencement of hospice care that certain items, services or drugs were not covered by the hospice include:

- An incident was reported to the Medicare Beneficiary Ombudsman Office by a hospice beneficiary who stated that when she ran out of her

[38] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Instruction-and-Form-for-Hospice-and-Medicare-Part-D.pdf.*

[39] The four categories of drugs listed above are not included in the analyses of maintenance drugs.

[40] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2016-11-15-Part-D-Hospice-Guidance.pdf.*

[41] *https://www.cms.gov/Center/Special-Topic/Ombudsman/How-the-Medicare-Beneficiary-Ombudsman-Works-for-You.pdf.*

diabetic test strips, the hospice refused to furnish them. The patient stated that the diabetic glucose testing was necessary to ensure the appropriate dosage of medication to control her blood glucose level, and hence prevent any symptoms that would be associated with hyperglycemia. When contacted, the hospice informed the Ombudsman that the hospice determined the patient's diabetes was not related to the patient's principal diagnosis of congestive heart failure (CHF) and thus the hospice was not furnishing any services to manage the patient's diabetes. While this hospice told the patient that her diabetes was unrelated to her congestive heart failure, they did not do so until after the beneficiary elected hospice and ran out of her test strips. The beneficiary disagreed with that determination but was not made aware of options for advocacy to assist in resolving this disagreement with the plan of care. Because of this lack of communication, the beneficiary felt she had no choice but to obtain her test strips and pay for them herself.

- A family member contacted CMS on behalf of his mother and stated that the hospice refused to furnish a seated walker because the hospice had determined the need for a seated walker was unrelated to the beneficiary's terminal illness and related conditions. This beneficiary was unable to ambulate without having to stop and sit down because of shortness of breath due to her end-stage lung cancer. The family member mentioned that his father was going to purchase the walker out of pocket, but he wanted to check with Medicare before doing so. The beneficiary was very distressed because being able to ambulate in her own home lessened the pain of lying in bed for prolonged periods of time and improved the quality of her life. The family member stated he did not know whom to call because he was under the impression that hospice was to cover everything his mother needed.
- During a CMS field office site visit, one hospice beneficiary reported that the hospice would not cover the cost of his benign prostatic hypertrophy (BPH) medication as the hospice stated the medication was unrelated to his terminal illness and related conditions. This medication helped alleviate urinary retention which caused him significant discomfort. This beneficiary had a hospice-reported principal diagnosis of sepsis due to a urinary tract infection. The beneficiary obtained his BPH medication through his pharmacy benefit but he stated he thought hospice was to provide him with all of his medications because that was the impression the hospice had given him when he elected hospice. He said he was never told by the hospice what medications or services he would have to obtain on his own.
- CMS has received multiple reports of hospice beneficiaries requiring palliative chemotherapy or palliative radiation for pain and symptom management, but these beneficiaries are told by hospices that these services are not covered under the hospice benefit because these treatments are curative in nature and therefore not in alignment with the hospice philosophy of care. These beneficiaries report that they were not told this when they elected hospice and they revoked the hospice benefit in order to receive needed treatments to alleviate pain.
- Similarly, CMS has met with physician associations to discuss the Medicare hospice benefit and physicians report that when they try to refer patients to hospice who require palliative blood transfusions for symptom management, the physicians and their patients are being told by hospices that the Medicare hospice benefit does not cover palliative blood transfusions. The physicians reported that they either do not refer these patients to hospice to ensure that the patients can continue their palliative blood transfusions, or for those patients that do elect the hospice benefit, those patients revoke hospice care to receive their palliative blood transfusions and then re-elect hospice care after they have received these services. We note that the Medicare hospice benefit does cover services for pain and symptom management, including palliative chemotherapy, radiation and blood transfusions. The per diem payment amounts paid to hospices account for such services and hospices are required to cover those items, services, and drugs for the palliation and management of the terminal illness and related conditions.

The continued anecdotal reports we receive from various stakeholders may suggest that some hospices are not adequately informing hospice patients at hospice election about the scope of services covered under the hospice benefit and thus hospice patients may not have complete benefit coverage information when electing the hospice benefit. This lack of coverage transparency may result in hospice patients having to seek out needed items, services and drugs outside of the Medicare hospice benefit and incur unexpected financial liability as a result. This also may suggest that hospices could be making care plan decisions based on cost or convenience rather than based on the needs, preferences and goals of the patient. This is not in alignment with the Medicare hospice benefit regulations and CoPs. We expect that services received outside of the hospice benefit to be rare.

Since the implementation of the Medicare hospice benefit, we have received frequent requests, via informal means and through the formal rulemaking process to provide additional guidance about determining what are considered ''related conditions'' as these are the coverage responsibility of hospice. Our position has been the same since the implementation of the Medicare hospice benefit in 1983. We believe that hospices are required to provide virtually all of the care needed by the terminally ill individual (48 FR 56010). Any services needed outside of the hospice benefit (that is, ''unrelated'') should be exceptional and unusual. We reiterate that the terminally ill individual's unique clinical condition makes it necessary for these determinations of related versus unrelated conditions to be made for each patient. To be responsive to the numerous requests for more guidance, in recent years' rules we have provided additional guidance regarding eligibility requirements for hospice admission (79 FR 50470 and 80 FR 25878); assessment of other conditions and comorbidities (80 FR 25878 through 25879); and, reporting of related and unrelated conditions on hospice claims (80 FR 25880). However, in spite of the guidance provided, we continue to have concerns that these decisions are based on a more narrow view of the overall condition of the individual, as is evidenced by the non-trivial amount of items, services, and drugs for potentially related conditions provided by non-hospice providers to beneficiaries under a hospice election.

4. Proposed Election Statement Content Modifications and Proposed Addendum To Provide Greater Coverage Transparency and Safeguard Patient Rights

As mentioned previously, the CoPs at § 418.56 require that the hospice include all services needed for the palliation and management of the terminal illness and related conditions on the individualized hospice plan of care. Similarly, the hospice interpretative guidelines for § 418.56 state that the plan of care should also identify the conditions or symptoms that the hospice determines to be ''unrelated'' so hospices can provide ongoing sharing of information with

other non-hospice healthcare providers who may be furnishing services unrelated to the terminal illness and related conditions.[42] Although hospices are required to educate each patient and the primary caregiver(s) on the services identified on the plan of care and document the patient's or representative's level of understanding, involvement, and agreement with the plan of care, the amount and nature of the non-hospice services being billed to Medicare outside of the hospice benefit suggests that hospice beneficiaries may not be fully informed, at the time of admission or throughout the hospice election, of the items, services, and drugs the hospice has determined to be unrelated to their terminal illness and related conditions. This is necessary information for patients and their families to make informed care decisions and to anticipate any financial liability associated with needed items, services, and drugs not provided under the Medicare hospice benefit.

The Medicare hospice regulations and CoPs are designed to ensure comprehensive coverage of hospice services and to help educate patients and their families regarding the scope of hospice services. Patient protection, empowerment, and advocacy are of such utmost importance that the CoPs at § 418.52 explicitly require that the hospice inform the patient of his or her rights and promote the exercise of these rights. However, as described in section III.C.3 above, we have concerns about whether patients are being adequately informed about the scope of services covered under the Medicare hospice benefit and whether patient rights are being fully promoted and protected. Furthermore, we continue to be concerned about the currently reported poor or absent communication between hospice and non-hospice providers needed to ensure coordination of all reasonable and necessary services for Medicare hospice beneficiaries. This may result in a lack of coverage transparency and where beneficiaries are unaware of their financial liability while under a hospice election for those items, services, and drugs the hospice has determined to be unrelated to their terminal prognosis.

Patients and their families must be provided complete and accurate information regarding their hospice benefit under Medicare, as well as their rights, responsibilities, and financial liability to ensure that they are empowered to make informed treatment decisions that align with their personal needs, preferences, and goals. In order to receive services under the Medicare hospice benefit, the beneficiary must make a choice to elect the benefit. As with all medical choices, this would mean that the beneficiary (or representative) has given informed consent for services. Stated simply, informed consent in medical care, which includes hospice care, is a process of communication between a clinician and a patient that results in the patient's authorization or agreement to undergo a specific medical intervention or mode of care.[43]

Therefore, we are proposing to modify the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election. In addition to the existing election statement content requirements at § 418.24(b), we are proposing that hospices also would be required to include the following on the election statement:

- Information about the holistic, comprehensive nature of the Medicare hospice benefit;
- A statement that, although it would be rare, there could be some necessary items, drugs, or services that will not be covered by the hospice because the hospice has determined that these items, drugs, or services are to treat a condition that is unrelated to the terminal illness and related conditions.
- Information about beneficiary cost-sharing for hospice services.
- Notification of the beneficiary's (or representative's) right to request an election statement addendum that includes a written list and a rationale for the conditions, items, drugs, or services that the hospice has determined to be unrelated to the terminal illness and related conditions and that immediate advocacy is available through the BFCC–QIO if the beneficiary (or representative) disagrees with the hospice's determination.

Likewise, we are proposing to make the corresponding regulations text changes at § 418.24(b).

Additionally, we are proposing that hospices would be required, upon request, to provide to the beneficiary (or representative) an election statement addendum with a list and rationale for the conditions, items, services, and drugs that the hospice has determined as unrelated to the terminal illness and related conditions. Similarly, we are proposing that hospices would be required to provide the election statement addendum upon request to other non-hospice providers that are treating such conditions, and Medicare contractors who request such information. We are proposing that if the election statement addendum is requested at the time of hospice election, the hospice must provide this information, in writing, to the individual (or representative) within 48 hours of the request. Furthermore, we are proposing that if this addendum is requested during the course of hospice care, the hospice must provide this information, in writing, immediately to the requesting individual (or representative), non-hospice provider, or Medicare contractor, as this information should be readily available in the beneficiary's hospice medical record. While we believe that hospices should be able to immediately provide this information, in writing, to the requesting beneficiary (or representative), non-hospice provider or Medicare contractor, we are soliciting comment on the appropriate timeframe to provide this information to the requesting party if such information is requested after the election of hospice care. During the course of hospice care, if there are changes to the plan of care that result in a determination that a new illness or condition has arisen, we are proposing that hospices would be required to issue an updated addendum to the patient (or representative) reflecting whether or not items, services and supplies related to the new illness or condition will be provided by the hospice.

The purpose of the proposed addendum is to inform beneficiaries and their families of non-covered conditions, items, services, and drugs to provide full coverage transparency to hospice patients and their families to assist in making treatment decisions. Likewise, the addendum will help facilitate communication and benefit coordination between hospices and non-hospice providers. We propose that if there is a request for the addendum, the presence of the signed addendum (and updated, signed addenda) in the beneficiary's hospice medical record would be a new condition for payment for Medicare hospice services.

Hospices can develop and design the addendum to meet their needs, similar to how hospices develop their own hospice election statement. We propose the addendum would be titled ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs.'' We propose that the addendum would include the following information:

1. Name of the hospice;

[42] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf* (L-Tag 538).

[43] *https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf.*

2. Beneficiary's name and hospice medical record identifier;

3. Identification of the beneficiary's terminal illness and related conditions;

4. A list of the beneficiary's current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;

5. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation would be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs is related is made for each patient and that the beneficiary should share this clinical explanation with other health care providers from which they seek services unrelated to their terminal illness and related conditions;

6. References to any relevant clinical practice, policy, or coverage guidelines.

7. Information on the following domains:

a. Purpose of Addendum

i. The purpose of the addendum is to notify the hospice beneficiary (or representative) of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the beneficiary's terminal illness and related conditions.

ii. The addendum is subject to review and shall be updated, as needed, when the plan of care is updated in accordance with § 418.56. The hospice will provide these updates, in writing, to the beneficiary (or representative).

b. Right to Immediate Advocacy

The addendum must include language that immediate advocacy is available through the BFCC–QIO if the beneficiary (or representative) disagrees with the hospice's determination. Specifically, the language must include contact information for the BFCC–QIO, as well as, the following statement: ''*We encourage you to contact your hospice provider to discuss any concerns about the diagnoses/conditions, as well as items, services, and medications listed on this form that you believe should be covered by the hospice. Beyond issues related to Medicare coverage, if you believe that your care concerns were not adequately addressed by your hospice provider, you may contact the Medicare Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO) to help you. While it cannot require services be covered, provided, or be paid for by Medicare, the BFCC–QIO addresses quality of care issues for people with Medicare. There are various ways the BFCC–QIO can assist you: (a) verbally engaging providers on your behalf to seek quick resolution, known as Immediate Advocacy, or (b) by having an independent physician review of your medical documentation to determine if there was a quality issue.*''

8. Name and signature of Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary's agreement with the hospice's determinations.

Finally, we are proposing to add the election statement addendum content requirements to the regulations at § 418.24.

As discussed and proposed above, the signed addendum (and any signed updates) would be a new condition for payment. This does not mean that in order to meet this condition for payment that the beneficiary (or representative), or non-hospice provider must agree with the hospice's determination. For purposes of this condition for payment, the signed addendum is only acknowledgement of the beneficiary's (or representative's) receipt of the addendum (or its updates) and this payment requirement would be met if there was a signed addendum (and any signed updates) in the requesting beneficiary's medical record with the hospice. This addendum would not be required to be submitted with any hospice claims. Likewise, the hospice beneficiary (or representative) would not have to separately consent to the release of this information to non-hospice providers furnishing services for unrelated conditions as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient's express authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient (45 CFR 164.506).

This hospice election statement addendum would only be required for Medicare hospice beneficiaries who request such information, though hospices may choose to provide this addendum to all of their hospice patients, regardless of payer source (after making appropriate adjustments for the specific payer). Hospices can determine which member of the IDG would be responsible for completing this addendum, but we would expect that this typically would be the function of the hospice registered nurse responsible for the patient's plan of care. As mentioned previously, hospices must designate a registered nurse (RN), who is a member of the IDG, to coordinate implementation of the comprehensive plan of care. The designated RN must assure that coordination of care and continuous assessment of patient, family, and caregiver needs occur among staff providing services to the patient, family, and caregiver so that all IDG members are kept informed of the patient/family/caregiver's status (§ 418.56(a)).

While ideally this addendum would be provided to the requesting beneficiary (or representative) at the time of hospice election, we recognize that hospices may need some leeway to have discussion amongst the members of the IDG to finish developing the hospice plan of care. Therefore, we are proposing that the addendum would be required to be provided to the requesting beneficiary (or representative) within 48 hours of the hospice election date; and the beneficiary would sign the addendum and receive a completed, signed copy at that time for his/her records. This is in alignment with the current CoP requirements at § 418.54(a) stating that the hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care. Hospices would be exempt from completing this addendum if the beneficiary died within 48 hours of the election date of hospice care. The original beneficiary or representative-signed election statement and addendum would be included in the patient's hospice medical record as already required by the hospice CoPs at § 418.104(a)(2).

If the beneficiary (or representative) requests this addendum after admission to hospice, we are proposing that the hospice would provide the addendum immediately to the beneficiary (or representative), as this information should already be readily available in the beneficiary's hospice medical

record. Additionally, we are proposing that hospices would be required, upon request, to provide a copy of the addendum (with the list of non-covered items, services and drugs) to non-hospice providers rendering services to the hospice beneficiary to support the hospice's determination that those items, services, or drugs are for unrelated conditions. Likewise, if there are any changes to the conditions, items, services, and/or drugs listed on the addendum that occur after the hospice election and during the course of hospice care, the hospice would update the addendum accordingly and the beneficiary would sign and date any updates to acknowledge that he/she has received the information. This would occur for both additions to and removal of any unrelated conditions, items, services, and/or drugs. However, we do not expect that additions to addendum would be a frequent occurrence. Body systems are interrelated and as an individual progresses closer to death, all care is related to the dying process and thus we would not expect to see unrelated conditions, items, services, or drugs routinely added to the addendum.

While the proposed election statement addendum outlines the content requirements for the addendum, it does not mandate the use of a specific form. Hospices are able to design the addendum in the form or format that best meets their needs, assuming all content requirements are met. As there is currently a model election statement available in a MLN Matters® article, SE1631,[44] we also will assist hospices in developing the addendum. If finalized, we would post a model election statement with the added content requirements, as well as a model addendum on the Hospice Center web page to help hospices in developing their addendums and thereby minimizing their costs.

Furthermore, Part D plan sponsors currently have a prior authorization process in place for their member enrolled in hospice for the four categories of drugs (analgesics, anti-nausea, anti-anxiety, and laxatives) and a voluntary, standardized form was developed with industry input for hospices to submit to Part D plans in order to assist in: (1) Proactively avoiding a drug claim from rejecting at point-of-sale; (2) overriding a reject edit at point-of-sale; and (3) communicating a change in the a patient's hospice status.[45] Hospices currently can use the standardized PA form as a means of notifying a Part D plan that their member has elected hospice care, as well as to document specific drugs that are or are not being covered by the hospice. As such, we intend to work with hospices and Part D plans to develop a process in which the ''Patient Notification of Hospice Non-covered Items, Services and Drugs'' potentially could be used at the point-of-service when hospice beneficiaries are filling drug prescriptions to ensure timely access to needed drugs. Complete documentation on the part of the hospice, coupled with timely notification of Part D sponsors, mitigates the risk for possible double payment by the Medicare program for drugs, and is anticipated to prevent Part D enrollees in hospice from having a hospice-related medication billed by a pharmacy to their Part D plan, potentially subjecting the beneficiary to out-of-pocket expenses.

While the CoPs already require that information on unrelated conditions should be documented and communicated to beneficiaries and non-hospice providers (§ 418.56), we believe that making this a condition for payment will help to ensure that hospices are diligent in providing this information to Medicare hospice beneficiaries. It is important to note that the proposed modifications to the hospice election statement and the election statement addendum, ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs,'' leverages existing hospice regulations, CoPs, and QIO requirements for hospices to:

- Identify those conditions and services present on hospice admission (and at plan of care update, as necessary) that the hospice has determined to be unrelated to the terminal illness and related conditions (§§ 418.22, 418.54(c)(2), 418.102), as outlined in element 4 of the addendum as noted above;
- Inform the beneficiary and family about what is covered and not covered by the hospice on the plan of care (§§ 418.52 and 418.56(b)), as outlined in the proposed additional election statement content requirements and elements 3, 4, 5, and 6 of the addendum as noted above;
- Coordinate with providers that are providing care unrelated to the terminal illness and related conditions (§ 418.56(e)(5)), as outlined in the proposed, additional election statement content requirements and elements 4, 5, and 6 of the addendum as noted above; Educate beneficiaries about their patient rights (§§ 418.52(a) and 476.78(b)(3)), as outlined in the proposed, additional election statement content requirements and element 7 of the addendum as noted above.

We believe that the election statement addendum will promote greater transparency regarding coverage under the Medicare hospice benefit, as well as informing the beneficiary as to those services they might need to seek outside of the hospice benefit. This would help in beneficiary decision-making regarding needed items, services, and drugs, and to determine the model of care that best meets their treatment preferences and goals of care. Likewise, we believe the addendum would provide information that would allow hospice beneficiaries to anticipate potential financial liability for health care services outside of the hospice benefit. Because hospices would have to provide a list and clinical rationale for those items, services, and drugs that they will not be covering because the hospice has determined them to be unrelated to the terminal illness and related conditions, to requesting hospice beneficiaries (or representatives), non-hospice providers rendering services to hospice beneficiaries, and/or Medicare contractors, we believe this accountability may mitigate unnecessary financial burden for hospice beneficiaries. A primary goal of the election statement addendum is to hold hospices more accountable to hospice beneficiaries through benefit coverage transparency. Hospices should already be holistic and comprehensive in their approach to the provision of hospice services. We believe this proposal would be an incremental step in ensuring beneficiaries are receiving information regarding the full scope of Medicare hospice benefits. Subsequently, if the proposed addendum is finalized, we would continue to monitor hospice utilization trends, including non-hospice spending, to determine whether any additional changes may be warranted.

As the hospice regulations and the CoPs already require the assessment and documentation of unrelated conditions as described throughout this section, we believe there is no increase in hospice burden resulting from this addendum requirement to communicate with non-hospice providers. Similarly, we believe the collection of information for the election statement and the addendum is already accounted for in the hospice CoP burden estimates in its information collection request (OMB control number: 0938–1067) that was re-

[44] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1631.pdf.*

[45] Hospice Information for Medicare Part D Plans, OMB-approved form (No. 0938–1269).

approved in November, 2017.[46] However, we estimate a one-time hospice cost burden to develop the election statement addendum, as well as a small increase in the time spent to complete the addendum. This estimate is described in section IV of this proposed rule. We believe that this election statement addendum would serve to streamline existing regulatory requirements into a single tool for communicating with beneficiaries and their families, the beneficiary's designated independent attending physician (if any), as well as, with non-hospice providers furnishing items, services, and drugs to hospice beneficiaries. As the addendum should also be used to provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions, as required by the CoPs, it would likely minimize time spent by IDG members looking through a beneficiary's medical record to locate the information on unrelated conditions, items, services, and drugs when such information is requested by non-hospice providers.

Furthermore, this addendum, if filled out completely, updated regularly, and shared proactively and in a timely manner with non-hospice providers and pharmacies, would minimize multiple calls from non-hospice providers and pharmacies to the hospice requesting information on a patient's unrelated conditions, items, services, and drugs since the addendum would provide this comprehensive information in a practical, consistent, and useful format. In effect, this addendum would reduce burden for non-hospice providers because this addendum could assist in making treatment decisions and support the coding of an appropriate modifier or condition code on non-hospice claims for services unrelated to the terminal illness and related conditions. Non-hospice providers providing services to hospice beneficiaries are required to report the following on Medicare claims to identify that the items or services were for the treatment of conditions unrelated to the terminal illness and related conditions:

- Institutional providers would submit a claim with condition code 07.
- Physicians would submit a claim with modifier GW.

The election statement addendum may allow the non-hospice provider to be ''without fault'' if there is any question regarding an overpayment. In accordance with section 1870 of the Act, a provider is responsible for an overpayment if the provider knew or had reason to know that service(s) were not reasonable and necessary, and/or the provider did not follow correct procedures or use care in billing or receiving payment. If non-hospice providers have the addendum, this potentially could satisfy section 1870 of the Act in providing that the non-hospice provider did not have reason to know that the services were not reasonable and necessary (considering the service itself is reasonable and necessary and satisfies all other requirements for payment). Moreover, if a non-hospice provider submits a claim to Medicare for services provided to a beneficiary that are unrelated to the terminal illness and related conditions but does not have the supporting documentation that the services are unrelated, this could be considered a false claim under the False Claims Act.[47] Having the addendum identifying the unrelated conditions, items, services, and drugs may provide the necessary documentation support that the non-hospice provider was rendering services unrelated to the terminal illness and related conditions. Therefore, the addendum could assist in more accurate claims submission, mitigate potential duplicative payments, and provide non-hospice providers with documentation to support a ''without fault'' determination. To provide transparency in how we believe this addendum reduces non-hospice provider burden, we have included a burden reduction estimate in section IV of this proposed rule. While this burden estimate assumes that an itemized list would be requested by every hospice beneficiary (or representative) receiving non-hospice services, or by the non-hospice providers rendering these unrelated services, we believe the actual burden would be less as hospices are already required to be comprehensive in their approach to covered services. As such, there would be hospices that would not have to complete the addendum as the hospice would be providing all items, services, and drugs.

We note that this addendum is not to be used by hospices as a vehicle in which to exercise unlimited ability to determine services as unrelated to the terminal illness and related conditions. It has always been CMS' expectation that hospice would be providing virtually all of the care needed by terminally ill individuals (48 FR 56010). Similarly, in a 1993 HCFA (now CMS) ruling, ''Weight To Be Given To a Treating Physician's Opinion In Determining Medicare Coverage Of Inpatient Care In a Hospital Or Skilled Nursing Facility,'' we stated that even though a physician's opinion is very important in making treatment determinations, no presumptive weight should be assigned to the treating physician's medical opinion alone, as coverage decisions are not made solely on this opinion.[48] That is, while the physician's determination carries great weight, other factors such as the condition of the patient upon admission, the nature of the principal diagnosis and the existence of comorbid conditions play an important role in coverage determinations. Hospices are to continue to make determinations about unrelated conditions, items, services, and drugs for each patient taking into account the needs, preferences and goals of the terminally ill individual and his or her family. In doing so, hospices are to conduct a thoughtful review of all of the beneficiary's conditions, related and unrelated to the terminal illness and related conditions, and current clinically relevant information supporting all diagnoses as required by regulation at § 418.25. This process requires clinical judgment in which hospices need to consider clinical practice guidelines and relevant research when making determinations of whether items, services, and drugs are related or unrelated to the terminal illness and related conditions.

We believe that the proposed election statement addendum, as a condition for payment, will achieve the goal of increasing comprehensive patient education, awareness, empowerment, and coverage transparency by:

- Providing information to the beneficiary (or representative), upon request, regarding those conditions, items, services, and drugs not covered by the hospice in an uncomplicated written format;
- Promoting informed consent;
- Encouraging discussion between the hospice and the terminally ill individual and their family regarding hospice covered and non-covered conditions, items, services, and drugs;
- Safeguarding patient rights and protecting the integrity of the hospice benefit by informing beneficiaries of an already established process through

[46] *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201809-0938-005.*

[47] The False Claims Act, Title 3, section 3729. *https://www.govinfo.gov/content/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31.pdf.*

[48] HCFA Ruling No. 93–1, ''Weight to Be Given to a Treating Physician's Opinion in Determining Medicare Coverage of Inpatient Care in a Hospital or Skilled Nursing Facility,'' May, 1993. *https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/HCFAR931v508.pdf.*

which they are able to receive BFCC–QIO Immediate Advocacy to dispute the hospice's determination regarding non-covered items and services for unrelated conditions when the beneficiary thinks they might be related;

- Providing a communication mechanism between hospice and non-hospice providers to help ensure benefit coordination for terminally ill patients.

This proposal outlines the modifications to the election statement content requirements and the required elements of the election statement addendum that we would require; we expect that hospices should already be complying with the existing, underlying coverage requirements. We are soliciting public comment on all aspects of the proposed modifications to the election statement content requirements, and the proposed election statement addendum, ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs,'' as described in this section as well as the corresponding proposed revision to the regulations at § 418.24(b) in section VI of this proposed rule.

D. Request for Information Regarding the Role of Hospice and Coordination of Care at End-of-Life

The Medicare hospice benefit is currently only available as part of traditional, fee-for-service (FFS) Medicare as hospice care is excluded from the scope of what Medicare Advantage (MA) plans must offer under section 1852(a)(1)(B)(i) of the Act. MA enrollees that are eligible for and elect the hospice benefit remain in their MA plan, but receive hospice care through traditional FFS Medicare. In turn, CMS pays hospice organizations directly for hospice services based on the FFS payment system. Generally, following the month the enrollee elects hospice, CMS pays the MA plan the rebate amount, but not the risk-adjusted capitated amount for Part A and Part B services. The MA plan remains responsible for the provision of supplemental benefits, and in the case of an MA–PD, Part D drugs that the hospice has determined are unrelated to the enrollee's terminal illness and related conditions. However, if the beneficiary requires items, services, or non-Part D drugs that the hospice has determined to be unrelated to the beneficiary's terminal illness and related conditions, then the costs for any treatment are borne by Medicare FFS rather than the MA plan in accordance with the MA program's special rules for hospice care at §§ 422.320(c)(3) and 417.585. Incorporating hospice into other kinds of care delivery models may be a way of alleviating the payment fragmentation described above.

As outlined above, the Medicare hospice benefit is currently only available as part of traditional FFS Medicare. As part of delivery system transformation, we seek information on the interaction of the hospice benefit and various alternative care delivery models, including MA, Accountable Care Organizations (ACOs), and other future models designed to change the incentives in providing care under traditional FFS Medicare. Finally, we seek information on the impact of alternative delivery and payment models implemented outside of the Medicare program on the provision of hospice care and any lessons learned that we should consider for the future design of the Medicare hospice benefit. The questions and complexities around incorporating hospice into MA are indicative of the operational considerations that would need to be addressed around any long-term programmatic change, especially with regards to other contexts, such as ACOs or other models or changes within the Medicare hospice benefit to adapt to a changing payor mix and environment. For example, with respect to MA, unless an alternative approach to building hospice into the current bid for Part A and B services were followed, county benchmarks and the risk adjustment model would need to be revised to incorporate the cost of these beneficiaries. Additionally, although alternative network approaches might be considered, incorporating hospice into MA could result in MA plans only contracting with a subset of local hospices, thereby potentially limiting patient access and choice, and network adequacy standards would need to be developed by CMS. Additionally, given that CMS cannot and should not interfere in the contracting process between MA plans and their contracted providers, if hospice providers agree to payment rates that are lower than what Medicare currently pays that may result in changes in the quantity and types of services provided. One way managed care or value-based arrangements could address these issues may be to construct payments for hospice care such that they align closely with how hospices are paid under traditional FFS Medicare.

We note that we are testing ways to incorporate hospice into other kinds of care delivery models to alleviate payment fragmentation. One approach is to test incorporating hospice into MA under the CMS Innovation Center's authority (section 1115A of the Social Security Act). Under this voluntary model, beginning in 2021, MA enrollees in participating plans will have hospice care provided through their chosen MA plan. Through this RFI, we are seeking public comments on other broader approaches, beyond the model noted above, regarding the appropriate role of hospice as part of the care options available. Specifically, we are seeking public comments on how hospice under Medicare FFS relates to other treatment options, how it impacts the provision of a spectrum of care for those that need supportive and palliative care before becoming hospice eligible and after, and whether rates of live discharge are a reflection of the current structure of Medicare FFS. We are also seeking comment on any care coordination differences for hospice patients that received Medicare through traditional FFS prior to hospice election, were enrolled in an MA plan prior to hospice election, or received care from providers that participate in an Accountable Care Organization (ACO) prior to hospice election. Finally, we are soliciting public comments on the pros and cons of including hospice services as the part of the benefits provided in value-based or capitated payment arrangements given that some hospices likely have experience with ACOs and experience with Medicaid managed care when providing hospice care through the Medicaid program, as well as experience in providing hospice care to patients enrolled in ''commercial coverage'' (non-Medicare/Medicaid managed care plans). We believe the information gathered under this RFI will help to inform: (1) Future CMS payment models; (2) the role hospice with respect to ACOs; and (3) our general understanding of the traditional FFS hospice environment in relation to the increasing penetration of managed care through the MA program.

E. Updates to the Hospice Quality Reporting Program (HQRP)

1. Background and Statutory Authority

The Hospice Quality Reporting Program includes meeting the reporting requirements for both the Hospice Item Set (HIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. Section 3004(c) of the Affordable Care Act amended section 1814(i)(5) of the Act to authorize a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. Depending on the amount

of the annual update for a particular year, a reduction of 2 percentage points could result in the annual market basket update being less than 0 percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the particular year involved. Any such reduction would not be cumulative nor be taken into account in computing the payment amount for subsequent FYs. Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary.

2. Update to Quality Measure Development for Future Years

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38622), we launched the Meaningful Measures initiative (which identifies high priority areas for quality measurement and improvement) to improve outcomes for patients, their families, and providers while also reducing burden on clinicians and providers. Meaningful Measures initiative is not intended to replace any existing programs, but will help programs identify and select individual measures. Meaningful Measure Initiative areas are intended to increase measure alignment across our programs and other public and private initiatives. Additionally, it will point to high priority areas where there may be gaps in available quality measures while helping guide our efforts to develop and implement quality measures to fill those gaps. More information about the Meaningful Measures initiative can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

The Meaningful Measures initiative fits well with the HQRP since it has changed little since we began with FY 2014 Hospice Wage Index and Payment Rate Update final rule, (76 FR 26806). The Meaningful Measures initiative enables us to review HQRP to close the gaps in quality measures to reflect the hospice industry as it has progressed to meet hospice care, including symptom management for its patients regardless of where hospice care is provided.

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48257), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the following 7 National Quality Forum (NQF)-endorsed measures for hospice:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen,
- NQF #1634 Pain Screening,
- NQF #1637 Pain Assessment,
- NQF #1638 Dyspnea Treatment,
- NQF #1639 Dyspnea Screening,
- NQF #1641 Treatment Preferences,
- NQF #1647 Beliefs/Values Addressed (if desired by the patient).

We finalized the following two additional measures in the FY 2017 Hospice Wage Index and Payment Rate Update final rule, effective April 1, 2017. Data collected will, if not reported, affect payments for FY 2019 and subsequent years. (81 FR 52163 through 52173):

- Hospice Visits when Death is Imminent,
- Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission. The Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission measure (hereafter referred to as ''the Hospice Comprehensive Assessment Measure'') underwent an off-cycle review by the NQF Palliative and End-of-Life Standing Committee and successfully received NQF endorsement in July 2017.

Data for the ''Hospice Visits when Death is Imminent'' measure pair is being collected using new items added to the HIS V2.00.0, effective April 1, 2017.

Our goal is to identify measures that provide a window into hospice care throughout the dying process, fit well with the hospice business model, and meet the objectives of the Meaningful Measures initiative. Quality measures should provide timely, understandable, comprehensive, clinically valid, and meaningful feedback to hospice leadership, all of its staff, and their different teams regardless of the hospice setting where care is provided. We seek public input on measure concepts and/or actual quality measures along with public comment on the discussions presented below.

a. Claims-Based and Outcome Quality Measure Development for Future Years

As part of Meaningful Measures initiative, we seek to develop claims-based and outcome measures as part of the future for the HQRP. While we acknowledge that there are limitations of using claims data as a source for measure development, there are several advantages to using claims data as part of a robust hospice quality reporting program. Claims-based measures place minimal burden on providers as they do not require additional data collection and data submission. Furthermore, in contrast to self-reported data that are dependent on hospice, patient, or caregiver participation, claims data has the benefit of following a relatively consistent format and of using a standard set of pre-established codes that describe specific diagnoses, procedures, and drugs. Additionally, nearly every encounter that a patient has with the healthcare system leads to the generation of a claim, creating an abundant and standardized source of patient information. This makes claims data widely available, relatively inexpensive, and amenable to analysis because they are readily available in an electronic format.

Medicare is the largest payer of hospice services and Medicare-certified providers predominate in hospice so it makes good sense to use claims data to reflect hospice care. Further, other settings, such as the Inpatient Quality Reporting Program (QRP) and the post-acute care (PAC) QRPs, have adopted claims-based measures, and the NQF has endorsed claims-based measures and believes they can capture quality even when not directly assessing clinical care. Although claims data have some limitations, such as incomplete reflection of care processes and patient outcomes, they will continue to be a valuable and important source of data for quality reporting for a selected set of metrics and as part of a hospice quality reporting program that includes other measures, such as HIS and CAHPS® Hospice Survey.

While not mutually exclusive of claims-based measures, we also seek to develop outcome measures as part of the Meaningful Measures initiative. Outcome measures could help with improving pain and symptom management, which is core to hospice care. They could also help identify the value of different staff providing care at different times in hospice. For these reasons, we plan to explore the development of other claims-based and outcome measures for the HQRP to work toward the high priority areas of reducing regulatory burden and identifying gaps in care. In identifying high priority areas for future measure enhancement and development, CMS takes into consideration input from all stakeholders including; Measures Application Partnership (MAP); the Office of the Inspector General (OIG); the Medicare Payment Advisory Commission (MedPAC); Technical

Expert Panels (TEP); issues raised through the Beneficiary and Family-Centered Care Quality Improvement Organization; and national priorities, such as those established by the National Priorities Partnership, the HHS Strategic Plan, the National Strategy for Quality Improvement in Healthcare, the CMS Quality Strategy, the Meaningful Measures initiative and the general public, such as through rulemaking. In addition, CMS considers feedback and input from published research and reports. We are not proposing any claims-based or outcome measures at this time. However, we are soliciting public comments and suggestions related to ideas for future claims-based and outcome measure concepts and quality measures in the HQRP that could also be tied to the goals of the Meaningful Measures initiative.

b. Update on Claims-Based Measure Development

The FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638), noted that, based on input from stakeholders, CMS has identified two ''high priority'' areas that will be addressed by claims-based measure development: Potentially avoidable hospice care transitions and access to levels of hospice care. The potentially avoidable hospice care transitions concept was developed as a measure under consideration called Transitions from Hospice Care, Followed by Death or Acute Care. The goal of this measure is to identify hospices that have notably higher rates of live discharges followed shortly by death or acute care utilization, when compared to their peers. Details about this measure can be found in the FY 2017 Hospice Wage Index and Payment Rate Update and the NQF website, *http://www.qualityforum.org/map/,* where it went on the measures under consideration (MUC) list in July 2018 and was reviewed by the MAP in December 2018. At this time, we are revisiting the potentially avoidable hospice care transitions. While MAP did not support the measure as specified, MAP recognized the impact that care transitions at the end of life can have on patients and suggested a number of ways MAP's concerns with the measure could be mitigated. Areas that the MAP recommended included reconsidering the exclusion criteria for the measure. Specifically, the exclusion for Medicare Advantage patients should be reviewed as this may be excluding too many patients. Additionally, the MAP suggested adding an exclusion to allow for patient choice, as there are a number of reasons a patient may choose to transition from hospice. For example, a patient may choose to pursue additional curative treatment, have cultural beliefs that influence the definition of a good death, have limited access to primary care, or may need to revoke the hospice benefit to avoid a financial penalty for seeking more acute care. MAP also noted that the measure may provide more useful information if it separates out the concepts addressed in the measure, as the measure may be trying to address different concepts by including both death within 30 days and admission to an acute care use within 7 days. The MAP also requested to consider shortening the timeframe for the measure, MAP 2019 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care, Final Report February 15, 2019, *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89400.*

The access to levels of hospice care measure concept is also detailed in the FY 2018 Hospice Wage Index and Payment Rate Update. After further analyses, it was determined that this measure concept as currently specified could result in hospices providing higher levels of care when it is not required by the plan of care or expected by CMS. We remain committed to developing claims-based measures that meet high priority areas and are rethinking both measures based on feedback from the MAP and our analyses. We are seeking public comment on ways to further develop these two measure concepts and different measure concepts that fall under these high priority areas.

c. Update on the Hospice Assessment Tool

We discussed the plan to develop a hospice assessment tool in the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements, (82 FR 36638). A technical expert panel on development of such an assessment tool was held in October 2017 followed by a pilot study that began with training 9 hospice sites in December 2017. We are sincerely thankful for and appreciative of the 9 Medicare hospices that participated in the pilot study. We learned much from them during the pilot study and afterwards in lessons learned interviews. Information from that pilot study, referred to as Pilot A, can be found on the HQRP website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HEART.html.* We also discussed Pilot A findings, lessons learned, and goals of a hospice assessment tool at the September 2018 special open door forum (SODF). The transcript for that SODF can be found at, *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html.* Key concepts in developing a hospice assessment tool include understanding the care needs of people through the dying process and ensuring the safety and comfort of individuals enrolled in hospice institutions nationwide. Currently we collect data at admission and discharge via HIS that are used to calculate measures in the HQRP. We would like to replace HIS and capture data with a hospice assessment instrument in order to bridge the gap to achieve a fuller understanding of patient care needs. While it must be recognized that hospice care differs from other PAC settings, there is a need to create a comprehensive assessment instrument for hospice care to align with other PAC settings, where feasible and practical. As such, objectives of a comprehensive assessment instrument must include the ability to establish goals of care that embrace the individual's values and preferences, and are consistent with a person-centered approach that values the person and caregiver in the care continuum with an emphasis on physical, psychosocial, spiritual, and emotional support. We continue our commitment to engaging stakeholders at regular SODF meetings and/or other means like the HQRP website, open door forums (ODF), webinars, and other sub-regulatory means.

One of the requests raised at the September 2018 SODF was to change the name of the hospice assessment tool from Hospice Evaluation Assessment Reporting Tool (HEART) to a name that is not as easily confused with other HQRP related tools like the Hospice Abstraction Reporting Tool (HART). We agree with this feedback since people refer to both by their same sounding acronyms and seek public comment on the name for the hospice assessment tool.

We will keep providers informed about future measure and assessment tool development efforts and solicit key stakeholder input through regular sub-regulatory channels. Additionally, future measure concepts under development, including details regarding measure definitions, data sources, data collection approaches, and timeline for implementation will be communicated in future rulemaking.

3. Form, Manner, and Timing of Quality Data Submission

a. Background

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act requires that beginning with the FY 2014 and for each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY.

b. Update on the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

Hospices are currently required to submit HIS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and the Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) as soon as FY 2020 that will enable us to make real-time upgrades, and we are designating that system as the data submission system for the Hospice QRP. Effective October 1, 2019, we are proposing to notify the public of any changes to the CMS-designated system in the future using sub-regulatory mechanisms such as web page postings, listserv messaging, and webinars. We are inviting public comment on this proposal.

4. CAHPS® Hospice Survey Participation Requirements for the FY 2023 APU and Subsequent Years

a. Background and Description of the CAHPS® Hospice Survey

The CAHPS® Hospice Survey is a component of the CMS HQRP which is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. Readers who want more information about the development of the survey, originally called the Hospice Experience of Care Survey, may refer to 79 FR 50452 and 78 FR 48261. National implementation of the CAHPS® Hospice Survey commenced January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

b. Overview of the CAHPS® Hospice Survey Measures

The CAHPS® Hospice Survey measures received NQF endorsement on October 26th, 2016 (NQF #2651). We adopted these 8 survey based measures for the CY 2018 data collection period and for subsequent years. These 8 measures are reported on Hospice Compare.

c. Data Sources

We previously finalized the participation requirements for the FY 2020, FY 2021, and FY 2022 APUs (see 82 FR 36673). We propose to extend the same participation requirements for the HQRP for FY 2023 and all future years. As part of the Patients Over Paperwork initiative, we solicit comments about the CAHPS Hospice Survey questionnaire. We seek comments regarding suggested changes, additions or deletions to the instrument that would improve its value to hospices for quality improvement and consumers for selecting a hospice.

d. Public Reporting of CAHPS® Hospice Survey Results

We began public reporting of the results of the CAHPS® Hospice Survey on Hospice Compare as of February 2018. We report the most recent 8 quarters of data on the basis of a rolling average, with the most recent quarter of data being added and the oldest quarter of data removed from the averages for each data refresh. We refresh the data 4 times a year in the months of February, May, August, and November.

e. Volume-Based Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a volume-based exemption for CAHPS® Hospice Survey Data Collection and Reporting requirements in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (82 FR 36671). We propose to continue our policy for a volume-based exemption for CAHPS® Hospice Survey Data Collection for FY 2021 and every year thereafter. For example, for the FY 2021 APU, hospices that have fewer than 50 survey eligible decedents/caregivers in the period from January 1, 2018 through December 31, 2018 (reference year) are eligible to apply for an exemption from CAHPS® Hospice Survey data collection and reporting requirements (corresponds to the CY 2019 data collection period). To qualify, hospices must submit an exemption request form for the FY 2021 APU. The exemption request form is available on the official CAHPS® Hospice Survey website: *http://www.hospiceCAHPSsurvey.org.* Hospices that intend to claim the size exemption are required to submit to CMS their completed exemption request form covering their total unique patient count for the reference year (for the CY 2019 data collection period the reference year is January 1, 2018 through December 31, 2018). The due date for submitting the exemption request form for the FY 2021 APU is December 31, 2019. Exemptions for size are active for 1 year only. If a hospice continues to meet the eligibility requirements for this exemption in future FY APU periods, the organization needs to request the exemption annually for every applicable FY APU period by the final day of the calendar year. Subsequent periods will follow the same pattern of using the year before the data collection year as the reference year for determining eligibility.

Starting with FY 2022 we propose to provide an automatic exemption to any hospice that (1) is an active agency and (2) according to CMS data sources has served less than a total of 50 unique decedents/caregivers in the reference year. The automatic exemption is good for 1 year and will be reassessed in subsequent years. Hospices with fewer than 50 unique decedents/caregivers in the reference year would not be required to submit an exemption request form.

Hospices that have a total patient count of more than 50 unique decedents/caregivers in the reference year, but who have a total of fewer than 50 survey-eligible decedents/caregivers will not be granted an automatic exemption. For example, hospices may have more than 50 unique decedents/caregivers, but have some decedents/caregivers who are not eligible to be sampled for the CAHPS Hospice Survey, which would therefore lead to fewer than 50 survey-eligible decedents/caregivers. Such hospices may qualify for a size exemption. To do so, they must apply for a size exemption by submitting the size exemption request form as outlined above. This exemption is valid for 1 year only. If the hospice remains eligible for the size exemption, it must request the exemption annually for every applicable FY APU period. We solicit feedback on these proposals.

TABLE 16—SIZE EXEMPTION KEY DATES 2021 THROUGH FY 2025

Fiscal year	Data collection year	Reference year	Size exemption form submission deadline
FY 2021	2019	2018	December 31, 2019.
FY 2022	2020	2019	December 31, 2020.
FY 2023	2021	2020	December 31, 2021.
FY 2024	2022	2021	December 31, 2022.
FY 2025	2023	2022	December 31, 2023.

f. Newness Exemption for CAHPS® Hospice Survey Data Collection and Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria as stated in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52181). In the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38642), we continued the newness exemption for FY 2023, FY 2024, FY 2025, and all future years. We encourage hospices to keep the letter they receive providing them with their CCN. The letter can be used to show when you received your number.

g. Survey Participation Requirements

We previously finalized survey participation requirements for FY 2022 through FY 2025 as stated in the FY 2018 and FY 2019 Hospice Wage Index and Payment Rate Update final rules (82 FR 36670 and 83 FR 38642 through 38643). We propose to continue those requirements in all subsequent years. Below we reprint the Hospice Survey data submission dates finalized in the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38643).

Sample months (month of death) [1]	CAHPS® quarterly data submission deadlines [2]
FY 2023 APU	
CY January–March 2021 (Quarter 1)	August 11, 2021.
CY April–June 2021 (Quarter 2)	November 10, 2021.
CY July–September 2021 (Quarter 3)	February 9, 2022.
CY October–December 2021 (Quarter 4)	May 11, 2022.
FY 2024 APU	
CY January–March 2022 (Quarter 1)	August 10, 2022.
CY April–June 2022 (Quarter 2)	November 9, 2022.
CY July–September 2022 (Quarter 3)	February 8, 2023.
CY October–December 2022 (Quarter 4)	May 10, 2023.
FY 2025 APU	
CY January–March 2023 (Quarter 1)	August 9, 2023.
CY April–June 2023 (Quarter 2)	November 8, 2023.
CY July–September 2023 (Quarter 3)	February 14, 2024.
CY October–December 2023 (Quarter 4)	May 80, 2024.

[1] Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).

[2] Data submission deadlines are the second Wednesday of the submission months, which are the months August, November, February, and May.

For further information about the CAHPS® Hospice Survey, we encourage hospices and other entities to visit: *https://www.hospiceCAHPSsurvey.org.* For direct questions, contact the CAHPS® Hospice Survey Team at *hospiceCAHPSsurvey@HCQIS.org* or telephone 1–844–472–4621.

5. Public Display of Quality Measures and Other Hospice Data for the HQRP

a. Background

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. These procedures shall ensure that a hospice has the opportunity to review the data that is to be made public prior to such data being made public; the data will be available on our public website.

To meet the Act's requirement for making quality measure data public, we launched the Hospice Compare website in August 2017. This website allows consumers, providers, and other stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. Since its release, the CMS Hospice Compare website has reported 7 HIS Measures (NQF #1641, NQF #1647, NQF #1634, NQF #1637, NQF #1639, NQF #1638, and NQF #1617). In February 2018, CAHPS® Hospice Survey measures (NQF #2651) were added to the website, and in November 2018, the Hospice and Palliative Care Composite Process Measure—Comprehensive Assessment at Admission (NQF #3235) was added to the website.

b. Update to Quality Measures To Be Displayed on Hospice Compare in FY 2019

1. Background and Description of ''Hospice Visits When Death Is Imminent'' Measure Pair

In the FY 2017 Hospice Wage Index and Payment Rate Update (81 FR 52163 to 52169, August 6, 2016), we finalized the ''Hospice Visits when Death is Imminent'' measure pair for

implementation April 1, 2017. This measure pair assesses whether the needs of hospice patients and their caregivers were addressed by the hospice staff during the last days of life. The ''Hospice Visits when Death is Imminent'' measure pair is made up of two measures, Measure 1 and Measure 2. Measure 1 of the pair assesses the percentage of patients receiving at least 1 visit from a registered nurse, physician, nurse practitioner, or physician assistant in the last 3 days of life. Measure 2 assesses the percentage of patients receiving at least 2 visits from social workers, chaplains or spiritual counselors, licensed practical nurses, or aides in the last 7 days of life.

2. Update to Public Reporting of the ''Hospice Visits When Death Is Imminent'' Measure Pair

As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643 to 38645, August 6, 2018), quality measures are added to Hospice Compare once they meet the readiness standards for public reporting, which is determined through rigorous testing for reliability, validity, and reportability. Since the proposal of the ''Hospice Visits when Death is Imminent'' measure pair, CMS has conducted further measure testing activities according to National Quality Forum (NQF) guidelines and the Blueprint for the CMS Measures Management System Version 14.0 available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf.* This testing is conducted to ensure that measures demonstrate scientific acceptability (including reliability and validity) and meet the goals of the HQRP, which include distinguishing performance among hospices and contributing to better patient outcomes.

As we assessed the scientific acceptability of ''Hospice Visits when Death is Imminent'' measure pair, we determined that Measure 1 meets established standards for reliability, validity, and reportability. Therefore, the measure will be publicly reported in FY 2019 as stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38645 to 38648). Our testing of Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair (referred to as Measure 2) revealed that the measure does not meet readiness standards for public reporting at this time and additional testing is needed before we are able to make a decision on the public reporting of Measure 2. Therefore, we have decided not to publish Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair at this time. See our discussion on our website: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Public-Reporting-Background-and-Announcements.html* for more information.

Although Measure 2 will not be publicly reported at this time, we believe that Measure 2 focuses on an important aspect of quality care for imminently dying patients. Therefore, we will include quality performance data on the measure in each hospice's confidential Quality Measure Reports and the Review and Correct Report available on the Certification and Survey Provider Enhanced Reporting (CASPER) system. Hospices will also still receive credit for reporting on Measure 2 as part of the HQRP requirements. Furthermore, Measure 2 aligns with our Meaningful Measures initiative and its quality priorities, particularly ''Strengthen Person and Family Engagement as Partners in Their Care—End of Life Care according to Preferences.'' While Measure 1 of the ''Hospice Visits when Death is Imminent'' measure pair (referred to as Measure 1) addresses case management and clinical care, Measure 2, which includes visits from social workers, chaplains or spiritual counselors, licensed practical nurses, and aides, recognizes providers' flexibility to provide individualized care from a variety of disciplines that is in line with the patient, family, and caregiver's preferences and goals for care and contributes to the overall well-being of the individual and others important to them at the end of life. As such, we believe that Measure 2 addresses a high-priority measure area where there is significant opportunity for improvement, as well as is meaningful to patients, clinicians, and providers alike.

We will conduct additional testing on Measure 2 to determine if and how the measure specifications may be modified or re-specified, and/or if the method for displaying the measure may be adjusted, so that this measure meets the highest standards of scientific acceptability and reportability. Additional testing will also ensure that Measure 2 is thoroughly evaluated to determine that it meets the criteria for display on Hospice Compare.

The results of the additional testing will inform the next steps regarding the public reporting of Measure 2 of ''Hospice Visits when Death is Imminent'' measure pair. As stated in the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38643), we will inform providers of updates to testing and public reporting of quality measures, including Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair, through sub-regulatory channels and regular HQRP communication strategies, such as Open Door Forums, Medicare Learning Network, CMS.gov website announcements, listserv messaging, and other opportunities.

While we have decided not to publicly report Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair on the Provider Preview Reports and Hospice Compare at this time, the measure will remain on provider's CASPER Quality Measure (QM) Reports. CASPER QM Reports are intended for providers' internal use and are meant to aid hospices in quality improvement efforts. Although the measure will not be publicly reported at this time, we believe that it is important for providers to internally review and be informed by these data, to ensure that they are providing their patients and caregivers the individualized support they need in the patients' last days of life. Our decision not to publicly report Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair at this time is distinct from our interest in continuing collecting these data. Specifically, these data are needed to determine whether a measure meets all the criteria for public reporting. Continued data collection will enable us to test and modify or re-specify a measure so that these criteria are satisfied. We seek to balance these data collection effort with the section 1814(i)(5)(E) of the Act, which states, ''The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the internet website of the Centers for Medicare & Medicaid Services.'' We believe that information required for the robust analyses to further develop this measure, modify or re-specify it to allow for public reporting justifies continuing data collection.

The data collection and submission requirements for the ''Hospice Visits When Death is Imminent'' measure pair will not change in order to collect the data for measure 1, which will be publicly reported beginning with FY 2019. Measure 2, which will not be publicly reported at this time, needs to be further evaluated for modification or re-specification. Measure 2 of ''Hospice Visits when Death is Imminent'' measure pair is calculated using items

O5010, O5020 and O5030 from the HIS V2.00.0. These items collect data on hospice visits in the final 3 days of life, level of care in the final 7 days of life, and hospice visits in the three to six days prior to death. Because the measure is not being removed from the HQRP, providers should continue to complete these items accurately and completely and submit HIS records to us in a timely manner. We require data from Section O to calculate Hospice Visits when Death is Imminent Measure 1, which will be publicly reported on Hospice Compare beginning in FY 2019. Therefore, we propose continued collection of this data to complete additional testing and to make a determination about the public reporting of Measure 2 of the ''Hospice Visits when Death is Imminent'' measure pair. We expect to complete our analysis by the end of FY 2020, and determine next steps for public reporting based on meeting established standards for reliability, validity, and reportability.

We are cognizant and respectful of the time and effort that hospices take to complete the HIS V2.00.0 items used to calculate and test Measure 2. We will continually evaluate the volume and robustness of the resulting data to determine when data collection is no longer required.

c. Display of Publicly Available Government Data on the Hospice Compare Website

1. Update to Posting of Public Use File (PUF) Data to the Hospice Compare Website

In the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (83 FR 38649), we finalized plans to publicly post information from the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (PUF) and/or other publicly available CMS data to the Hospice Compare website. This PUF data, along with clear text explaining the purpose and uses of this information and suggesting consumers discuss this information with their healthcare provider, will be displayed under a new ''General information'' section on Hospice Compare in summer 2019. This new section will precede the existing ''Family Experience of Care'' section on the Hospice Compare website. Tables 17 through 19 show how these data will displayed on Hospice Compare.

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Table 17: Mock-up of Level of Care Provided Information on Hospice Compare

Level of care provided in calendar years 2014, 2015, and 2016	**Hospice A Average Daily Census:** 345 **Date Certified:** 04/01/1995	**Hospice B Average Daily Census:** 67 **Date Certified:** 04/01/2002	**Hospice C Average Daily Census:** Not available **Date Certified:** 04/01/2017	**National Average Average Daily Census:** 74
Provided Routine Home Care only	✓		Not Available	3.1%
Provided Routine Home Care and other levels of care		✓	Not Available	96.9%

Note: Information is "Not Available" for Hospice C because the hospice was Medicare-certified in 2017. PUF data is only available through 2016.

Table 18: Mock-up of Primary Diagnosis Information on Hospice Compare

Medical Conditions	**Hospice A Average Daily Census:** 345 **Date Certified:** 04/01/1995	**Hospice B Average Daily Census:** 67 **Date Certified:** 04/01/2002	**Hospice C Average Daily Census:** Not available **Date Certified:** 04/01/2017	**National Average Average Daily Census:** 74
Cancer	18.3%	45.6%	Not Available	27.3%
Dementia	45.5%	20.7%	Not Available	21.1%
Stroke	Less than 11 patients	18.9%	Not Available	9.4%
Heart Disease	17.8%		Not Available	20.8%
Respiratory Disease		17.0%	Not Available	11.9%
Other	Less than 11 patients	Less than 11 patients	Not Available	16.1%

Note: Information is "Not Available" for Hospice C because the hospice was Medicare-certified in 2017. PUF data is only available through 2016. "Less than 11 patients" indicates the hospice served less than 11 patients with the indicated condition in 2016. Data for hospice providers who served between 0 and 11 patients with a particular condition is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

Table 19: Mock-up of Location of Care Information on Hospice Compare

Location	**Hospice A Average Daily Census:** 345 **Date Certified:** 04/01/1995	**Hospice B Average Daily Census:** 67 **Date Certified:** 04/01/2002	**Hospice C Average Daily Census:** Not available **Date Certified:** 04/01/2017	**National Average Average Daily Census:** 74
Home	✓	✓	Not Available	99.8%
Assisted Living Facility	✓	✓	Not Available	76.1%
Nursing Facility	✓	Less than 11 patients	Not Available	60.8%
Skilled Nursing Facility	Less than 11 patients	✓	Not Available	52.5%
Inpatient Hospital Facility	✓		Not Available	31.5%
Inpatient Hospice		Less than 11 patients	Not Available	17.0%

Facility				
All other locations	Less than 11 patients	✓	Not Available	17.6%

Note: Information is "Not Available" for Hospice C because the hospice was Medicare-certified in 2017. PUF data is only available through 2016. "Less than 11 patients" indicates the hospice served less than 11 patients in the indicated location in 2016. Data for hospice providers who served between 0 and 11 patients in a particular location is not reported in the PUF to protect personal health information and ensure publicly reported data is a reliable indication of services provided by the hospice.

2. Proposal to Post Information From Government Data Sources to the Hospice Compare Website

As part of our ongoing efforts to make the Hospice Compare website more meaningful and informative to our beneficiaries, their caregivers, and families, we propose to post information from other publicly available government data, in addition to the data from the PUF or other CMS sources, to the Hospice Compare website at some time in the future. We are proposing to be able to use informative data from other government sources on Hospice Compare in the future and as soon as FY 2020. Examples, provided for illustration, from where CMS could pull publicly available government data include the United States Census Bureau, Centers for Disease Control and Prevention, and National Institutes of Health.

We may use information available in these public government files to augment the ''General Information'' section described above. This ''General Information'' section including PUF data and, if this proposal is finalized, information from other public government data will provide additional information along with the HIS and CAHPS® quality measures that are already displayed.

Any future reporting of public government data on the Hospice Compare website will be displayed in a consumer-friendly format. This means we may display the data as shown in these publicly available government files or present the data after additional calculations. For example, the data could be averaged over multiple years, displayed as a percentage rather than the raw number, or other calculations could be based on a given year or over multiple years, so the data has meaning to end-users. Furthermore, by performing these calculations, we can make the data apply to hospices broadly regardless of size, location, or other factors.

Also, we would like to note that data used from these publicly available sources are not quality measures. Rather, they present supplementary information that many consumers seek during the provider selection process and, therefore, will help them to make an informed decision. This is similar to other useful information we already display on Hospice Compare under the Spotlight, Tools and Tips, and Additional Information sections on the Hospice Compare homepage. Data from publicly available data sources can serve as one more piece of information, along with quality of care metrics from the HIS and CAHPS® Hospice Survey and other useful information, to help consumers effectively and efficiently compare hospice providers and make an informed decision about their care in a stressful time. We also believe such information may be useful to providers. For example, adding information from the United States Census Bureau may help consumers better understand the service area in which they are looking for services (for example, if there is a large population of people from a similar race/ethnicity in the area). This information may also help providers better understand their service area to see if there are any business development opportunities (for example, if there is a large population of a similar race/ethnicity, the provider may consider investing resources in better serving patients from this background).

To ensure that end-users understand that these data provide information about hospice characteristics and are not a reflection of the quality of care a hospice provides, we will, with consultation from key stakeholders, carefully craft explanatory language to ensure that consumers understand the information and how the data are meant for informational purposes only.

As we determine which publicly available government data sources we will use and how we will be using and presenting information from these sources, we will inform the public and engage with stakeholders via sub-regulatory processes, including regular HQRP communication strategies such as Open Door Forums, Medicare Learning Network, Spotlight Announcements, and other opportunities.

We are soliciting public comment on our proposal to post information from publicly available government sources to the Hospice Compare website in the future.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. This data must be submitted in a form and manner, and at a time specified by the Secretary.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Election Statement Addendum: ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs''

To calculate this burden estimate, we use salary information from the Bureau of Labor Statistics (BLS) website at *https://www.bls.gov/* and include a fringe benefits package worth 100 percent of the base salary. The mean hourly wage rates are based on May, 2017 BLS data for each discipline. Table 20 contains our burden estimate assumptions for the proposed Election Statement Addendum: ''Patient Notification of Hospice Non-Covered

Items, Services, and Drugs'' discussed in section III.C. of this proposed rule.

TABLE 20—ELECTION STATEMENT ADDENDUM: ''PATIENT NOTIFICATION OF HOSPICE NON-COVERED ITEMS, SERVICES, AND DRUGS'' BURDEN ESTIMATE ASSUMPTIONS

Number of Medicare-billing hospices, from FY 2017 Medicare Enrollment Database, Provider of Service files.	4,465.
Number of hospice elections in FY 2017	(1,268,497 × 0.84) = 1,065,537.
Hourly rate of an office employee (Executive Secretaries and Executive Administrative Assistants, 43–6011).	$57.12 ($28.56 × 2.00).
Hourly rate of an administrator (General and Operations Managers, 11–1021)	$118.70 ($59.35 × 2.00).
Hourly rate of registered nurses (Registered Nurses, 29–1141)	$70.72 ($35.36 × 2.00).
Hourly rate of pharmacy technicians (Pharmacy Technicians, 29–2052)	$31.80 ($15.90 × 2.00).

Source: FY 2017 hospice claims data. 16 percent of beneficiaries die within the first 48 hours. Hospices are exempt for completing addendum if beneficiary dies within first 48 hours.

Section 1814(a)(7) of the Act requires for the first 90-day period of a hospice election the individual's attending physician (as defined in section 1861(dd)(3)(B) of the Act) (which for purposes of this subparagraph does not include a nurse practitioner), and the medical director (or physician member of the interdisciplinary group described in section 1861(dd)(2)(B) of the Act) of the hospice program providing (or arranging for) the care, each certify in writing, at the beginning of the period, that the individual is terminally ill (as defined in section 1861(dd)(3)(A) of the Act). The regulations codified at §§ 418.22 and 418.25 provide the requirements regarding the certification of terminal illness and admission to hospice care. The hospice medical director must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. Additionally, clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification. The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification. The aforementioned regulations also require that the hospice medical director must consider both related and unrelated conditions and current clinically relevant information when making the decision to certify the individual as terminally ill. Likewise, the hospice CoPs at § 418.102(b) provide the requirements regarding the certification responsibility of the hospice medical director or hospice physician designee which includes a review of the clinical information, including both related and unrelated conditions, for each hospice patient.

In order to receive hospice services under the Medicare hospice benefit, eligible beneficiaries must elect to receive hospice care by completing an election statement. By signing this election statement, the individual acknowledges that he/she waives all rights to Medicare payments for treatment related to the terminal illness and related conditions. The content requirements for the hospice election statement are listed at § 418.24(b) and each hospice election statement must include the following information:

- Identification of the particular hospice and of the attending physician that will provide care to the individual. The individual or representative must acknowledge that the identified attending physician was his or her choice.
- The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.
- Acknowledgement that certain Medicare services, as set forth in § 418.24(d), are waived by the election.
- The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.
- The signature of the individual or representative.

Once a beneficiary is certified as terminally ill and elects the Medicare hospice benefit, the hospice conducts an initial assessment visit in advance of furnishing care. During this visit, the hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities as required by the CoPs at § 418.52. Likewise, the regulations at § 476.78 state that providers must inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to Quality Improvement Organization (QIO) review.

The beneficiary needs identified in the initial and comprehensive assessments drive the development and revisions of an individualized written plan of care for each patient as required by the hospice CoPs at § 418.56. The hospice plan of care is established, reviewed and updated by the hospice IDG and must include all services necessary for the palliation and management of the terminal illness and related conditions. While needs unrelated to the terminal illness and related conditions are not the responsibility of the hospice, the hospice may choose to furnish services for those needs regardless of responsibility. However, if a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, the hospice is to communicate and coordinate with those health care providers who are caring for the unrelated needs, as described in § 418.56(e). In accordance with the CoPs, the hospice must document the services and treatments that address how they will meet the patient and family-specific needs related to the terminal illness and related conditions in the plan of care, and those needs unrelated to the terminal illness and related conditions that are present when the patient elects hospice should also be documented. This documentation ensures that the hospice is aware of those unrelated needs and who is addressing them. This documentation provides the support for the hospices' financial responsibility for the hospice services they will be providing. There is limited beneficiary financial liability for hospice services upon election of the Medicare hospice benefit. However, for any services received that are unrelated to the terminal illness and related conditions, the beneficiary would incur any associated copayments and coinsurance.

Hospices already are required to review, determine, and document information on unrelated conditions per the hospice regulations and CoPs. However, to ensure Medicare beneficiaries are provided disclosure of those conditions, items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions at the time of admission, we propose to add to the regulations at § 418.24(b) and (c), the requirement of an election statement addendum titled ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs'' that would be issued to the patient (or representative) within 48 hours of the hospice election date to ensure that Medicare beneficiaries are fully informed whether or not all items, services, and drugs identified on the hospice plan of care will be furnished by the hospice. The addendum statement would not be required if the beneficiary died within 48 hours of the hospice election date. This addendum would accompany the hospice election statement and each hospice would use the required proposed elements to develop and design their own addendum to best meet their needs and the requirement. This requirement for payment would be added to the regulations at § 418.24(b) and (c).

The burden associated with the documentation requirement for the addendum includes the time for each hospice to develop the addendum that the hospice provides to the beneficiary (or their representative) within 48 hours of election of the Medicare hospice benefit. The addendum must include the name of the issuing hospice, beneficiary's name, and hospice medical record identifier. The addendum must also allow the hospice registered nurse to document a list of non-covered conditions, items, services, and drugs, as well as provide a clinical explanation as to why these conditions, items, services, and drugs have been determined to be unrelated to the terminal illness and related conditions. This documentation would include references to any relevant clinical practice, policy, or coverage guidelines. The addendum must include statements informing the patient as to the purpose of the addendum and information on BFCC–QIO Immediate Advocacy rights and contact information. The addendum would be signed by the beneficiary as an acknowledgement that he or she has received this information, but signing it does not mean the beneficiary agrees with the determination. We believe that the burden for the hospice associated with the election statements addendum would be the cost of developing the form and the cost of filling out the form. There is no associated burden for hospices to communicate/coordinate with non-hospice providers regarding the content of the addendum statement because the hospice CoPs, as described above, have always required hospices to have a system of communication with non-hospice providers in place. However, we believe that the election statement addendum would reduce burden for non-hospice providers through a consistent and streamlined process by which non-hospice providers can make informed treatment decisions and accurately submit claims with the appropriate condition code or modifier.

1. Estimated Hospice Burden With Election Statement Addendum

a. Estimated One-Time Form Development

We estimate a one-time burden for the development of the election statement addendum. We estimate that it would take a hospice administrative assistant 15 minutes (15/60 = 0.25 hours) to develop the addendum with the required elements, and the hospice administrator 15 minutes (15/60 = 0.25 hours) to review the addendum. The clerical time plus administrator time equals a one-time burden of 30 minutes or (30/60 = 0.50 hours) per hospice. For all 4,465 hospices, the total time required would be (0.50 × 4,465) = 2,232.5 hours. At $57.12 per hour for an executive administrative assistant, the cost per hospice would be (0.25 × $57.12) = $14.28. At $118.70 per hour for the administrator's time, the cost per hospice would be (0.25 × $118.70) = $29.68. Therefore, the one-time cost, per hospice, for the development of the form would be ($14.28+29.68) = $43.96, and the total one-time cost for all hospices would be ($43.96 × 4,465) = $196,281.

b. Estimated Time for Hospice To Complete Addendum

Per the hospice CoPs at § 418.56(a), the hospice must designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The hospice CoPs at § 418.54 require that a registered nurse conduct the initial assessment, therefore, the registered nurse would be responsible for completing the addendum for each hospice election as part of the routine admission paperwork. We estimate that there would be 1,268,497 hospice elections in a year based on FY 2017 claims data. Approximately 16 percent of hospice beneficiaries die within the first 48 hours after the hospice election date. Hospices would not be required to complete the election statement addendum for those hospice beneficiaries that die within 48 hours of hospice election. Therefore, the estimated total number of hospice elections in FY 2020 that would require the hospice election statement addendum would be (1,268,497 × 0.84) = 1,065,537. There are 4,465 Medicare-certified hospices, so on average there would be (1,065,537/4,465) = 239 hospice elections per hospice. The estimated burden for the hospice registered nurse to extrapolate this information from the existing documentation in the patient's hospice medical record and complete this addendum would be 10 minutes (10/60 = 0.1667). At $70.72 per hour for a registered nurse over 10 minutes (0.1667 × $70.72 = $11.79), we estimate the total cost of RN time to complete the addendum per hospice in FY 2020 to be ($11.79 × 239) = $2,818, and the total cost of RN time to complete the addendum for all hospices in FY 2020 would be ($2,818 × 4,465) = $12,582,370. The estimated total per hospice and total annual hospice cost associated with the proposed addendum (including one-time form development and total RN costs) in FY 2020 are shown in table 21 below. These total costs would include the one-time development of the addendum, so subsequent years' costs would only include the cost for the RN to complete the addendum statement. Providing this information to the beneficiary would be part of the routine admissions process and, as such, incurs no additional burden to that process.

Table 21: FY 2020 Estimated Per Hospice and Total Hospice Costs for Election Statement Addendum

	Average # Of Elections Per Hospice	Total # of Hospice Elections (based on FY 2017)
Number of Hospice Elections	239	1,065,537
	Average Cost Per Hospice	Total Annual Costs for All Hospices
Total # of Hospices		4,465
One-time Form Development	$43.96	$196,281
RN Form Completion	$2,818	$12,582,370
Total Hospice Estimated FY 2020 Costs		$12,778,651

Source: FY 2017 CWF Claims Data, Medicare Enrollment Database, and Provider of Service (POS). Enrollment data.

2. Estimated Burden Reduction for Non-Hospice Providers

To ensure comprehensive and coordinated care, the CoPs at § 418.56(e) require hospices to have a communication system that allows for the exchange of information with other non-hospice health care providers who are furnishing care unrelated to the terminal illness and related conditions. Therefore, it is our expectation that hospices are already determining what is related and unrelated to the terminal illness and related conditions. The election statement addendum would add no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described above and in the preamble of this proposed rule. However, burden would be reduced for non-hospice providers, including institutional, non-institutional and pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions.

To estimate the cost burden reduction, we first calculated the estimated current burden, in the absence of the addendum, for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Next, we calculated the estimated burden, using the addendum for communicating and coordinating information regarding unrelated conditions between hospice and non-hospice providers. Finally, we analyzed the difference between the burden estimates to see if there is any overall reduction. To do this, we analyzed all Medicare Parts A and B non-hospice claims for beneficiaries under a hospice election in FY 2017. We also examined the Part D claims for drugs provided to hospice beneficiaries under a hospice election. Specifically, we analyzed the following:

- The total number of non-hospice, institutional claims with condition code 07 (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of non-hospice, non-institutional claims with ''GW'' modifier (to indicate the services were unrelated to the terminal illness and related conditions).
- The total number of Part D claims for beneficiaries under a hospice election.
- The average number of hospice beneficiaries per non-hospice provider with institutional claims with condition code 07.
- The average number of hospice beneficiaries per non-hospice provider with non-institutional claims with ''GW'' modifier.
- The average number of hospice beneficiaries per non-hospice provider with Part D claims.

To calculate the average number of hospice beneficiaries per non-hospice provider, we count the number of unique beneficiaries associated with each non-hospice provider as beneficiaries may receive services by more than one non-hospice provider. This means that some beneficiaries are double-counted. However, given this estimate is calculated based on the number of expected communication encounters between hospices and non-hospice providers, this is the appropriate approach. Because we double-counted beneficiaries, we expect that average to be larger than the ratio of unique beneficiaries to unique non-hospice providers. Table 22 below summarizes Part A, B and D claims that overlap with hospice episodes in FY 2017.

TABLE 22—SUMMARY OF PART A, B AND D CLAIMS THAT OVERLAP WITH HOSPICE EPISODES, FY 2017

Non-hospice claim type	Number of hospice beneficiaries	Number of non-hospice providers	Number of hospice providers	Average number of hospice benes per non-hospice provider
Part A & B, Non-Hospice Total	473,587	94,535	4,341	

TABLE 22—SUMMARY OF PART A, B AND D CLAIMS THAT OVERLAP WITH HOSPICE EPISODES, FY 2017—Continued

Non-hospice claim type	Number of hospice beneficiaries	Number of non-hospice providers	Number of hospice providers	Average number of hospice benes per non-hospice provider
Institutional Claims w/07	173,060	19,354	4,117	11.0
Non-Institutional Lines w/GW	431,379	75,181	4,321	12.0
Part D	591,543	60,632	4,416	12.0

Source: FY 2017 Parts A, B, and D claims.

3. Burden Estimate Without Election Statement Addendum for Non-Hospice Providers

In order for non-hospice providers to make treatment decisions regarding services, items and medications for hospice beneficiaries and to submit the appropriate modifier or condition code on Medicare claims, they need supporting information from the hospice regarding related and unrelated conditions. As such, we first estimate the current burden associated with this communication and coordination in the absence of the election statement addendum. We believe this would require the non-hospice providers to contact the hospice and have a detailed phone call to obtain and document the information on unrelated conditions, items, services, and medications. For non-hospice providers submitting institutional claims (including inpatient acute care hospitals, SNFs, HHAs, and institutional outpatient providers), typically nurse case managers provide coordination of care for those beneficiaries in these settings who are receiving inpatient services or who are preparing to transition to a post-acute care setting or home. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per institutional, non-hospice provider is 11 per year, which would mean each institutional, non-hospice provider would have an average of 11 communication encounters with hospice. The total number of institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,354. At $70.72 per hour for a registered nurse (0.25 × $70.72) = $17.68, we estimate the total cost per institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be ($17.68 × 11) = $194.48 and the annual total cost for all institutional, non-hospice providers in FY 2018 would be ($194.48 × 19,354) = $3,763,966.

For non-institutional, non-hospice providers (including physicians), we also expect that a nurse would contact the hospice to obtain the needed clinical information on unrelated conditions, items, services and drugs. The estimated burden for the registered nurse to contact the hospice to obtain the needed information would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 12 per year, which would mean each provider would have an average of 12 communication encounters with a hospice. The total number of non-institutional, non-hospice providers servicing hospice beneficiaries in FY 2017 was 75,181. At $70.72 per hour for a registered nurse (0.25 × $70.72) = $17.68, we estimate the total cost per non-institutional, non-hospice provider furnishing services to hospice beneficiaries in FY 2020 to be ($17.68 × 12) = $212.16 and the annual total cost for all non-institutional, non-hospice providers in FY 2018 would be ($212.16 × 75,181) = $15,950,401.

For Part D providers furnishing drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be 15 minutes (15/60 = 0.25). The average number of hospice beneficiaries receiving services per Part D pharmacy providing maintenance drugs is 12 per year, which would mean each pharmacy would have an average of 12 communication encounters with hospice. The total number of Part D pharmacies providing maintenance drugs to hospice beneficiaries in FY 2017 was 60,632. At $31.80 per hour for a pharmacy technician (0.25 × $31.80) = $7.95, we estimate the total cost per Part D pharmacy providing maintenance drugs to be ($7.95 × 12) = $95.40 and the annual total cost for all Part D pharmacies providing maintenance drugs to be ($95.40 × 60,632) = $5,784,293. The estimated total annual burden for all non-hospice providers furnishing services, items and medications to hospice beneficiaries in FY 2020 without the availability of the hospice election statement addendum identifying unrelated conditions, items, services and drugs would be $25,498,660 ($3,763,966 + $15,950,401 + $5,784,293).

4. Burden Reduction Estimate With Election Statement Addendum for Non-Hospice Providers

However, with the availability of the ''Patient Notification of Hospice Covered/Non-Covered Items, Services, and Drugs'' election statement addendum, we believe this estimated burden would be reduced for non-hospice providers through a streamlining of the communication and coordination process. For institutional, non-hospice providers (those who would submit claims for unrelated services with condition code 07), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced to 5 minutes (5/60 = 0.0833). The average number of hospice beneficiaries receiving services per institutional non-hospice provider is 11 per year. The total number of institutional non-hospice providers servicing hospice beneficiaries in FY 2017 was 19,354. At $70.72 per hour for a registered nurse (0.0833 × $70.72) = $5.89, we estimate the total cost per institutional non-hospice provider in FY 2020 to be ($5.89 × 11) = $64.79 and the annual total cost for all institutional non-hospice providers in FY 2020 would be ($64.79 × 19,354) = $1,253,945.66 an annual decrease in burden by ($3,763,966 − $1,253,945.66) = $2,510,020.34.

For non-institutional, non-hospice providers (those who would submit claims for unrelated services with modifier GW), the estimated burden for the registered nurse to contact the hospice to obtain the needed information would be reduced to 5 minutes (5/60 = 0.0833). The average number of hospice beneficiaries receiving services per non-institutional, non-hospice provider is 12 per year. The total number of non-institutional, non-hospice providers servicing hospice

beneficiaries in FY 2017 was 75,181. At $70.72 per hour for a registered nurse (0.0833 × $70.72) = $5.89, we estimate the total cost per non-institutional, non-hospice provider in FY 2020 to be ($5.89 × 12) = $70.68 and the annual total cost for all non-institutional, non-hospice providers in FY 2020 would be ($70.68 × 75,181) = $5,313,793.08, an annual decrease in burden by ($15,950,401 − 5,313,793.08) = $10,636,607.92.

For Part D pharmacies providing drugs to hospice beneficiaries, the estimated burden for the pharmacy technician at the point of service to contact the hospice to obtain the needed clinical information regarding the drugs deemed by the hospice as unrelated to the terminal illness and related conditions would be reduce to 5 minutes (5/60 = 0.0833). The average number of hospice beneficiaries receiving services per Part D pharmacy providing maintenance drugs is 12 per year. The total number of Part D pharmacies providing maintenance drugs to hospice beneficiaries in FY 2017 was 60,632. At $31.80 per hour for a pharmacy technicians (0.0833 × $31.80) = $2.65, we estimate the total cost per Part D pharmacy providing maintenance drugs to be ($2.65 × 12) = $31.80 and the annual total cost for all Part D pharmacies providing maintenance drugs to be ($31.80 × 60,632) = $1,928,097.60, an annual decrease in burden by ($5,784,293 − $1,928,097.60) = $3,856,195.40. The estimated total annual burden for all non-hospice providers furnishing services, items and drugs to hospice beneficiaries in FY 2020 with the availability of the hospice election statement addendum identifying unrelated conditions, items, services and medication would be $8,495,836.66 for an overall burden reduction of ($25,498,660 − $8,495,836.66) = $17,002,823.34. The total reduction in burden for all institutional, non-institutional, and Part D pharmacy non-hospice providers is summarized in table 23 below.

TABLE 23—FY 2020 ESTIMATED TOTAL OVERALL BURDEN REDUCTION FOR NON-HOSPICE PROVIDERS USING ELECTION STATEMENT ADDENDUM

Non-hospice claims	Burden without addendum	Burden with addendum	Estimated burden reduction for non-hospice providers
Institutional Claims with Condition Code 07	$3,763,966	$1,253,945	$2,510,021
Non-institutional Claims with GW Modifier	15,950,401	5,313,793	10,636,608
Part D Maintenance Drugs	5,784,293	1,928,098	3,856,195
Total Burden Reduction for Non-Hospice Providers	25,498,660	8,495,836	17,002,824

The use of the ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs'' election statement addendum would result in an estimated, total overall provider burden reduction of −$4,224,173 ($12,778,651 − $17,002,824) in FY 2020. Table 24 below summarizes the FY 2020 estimated total burden reduction.

TABLE 24—FY 2020 ESTIMATED TOTAL PROVIDER BURDEN REDUCTION USING ELECTION STATEMENT ADDENDUM

FY 2020 Estimated Cost for Election Statement Addendum	+$12,778,651
FY 2020 Estimated Non-hospice Provider Burden Reduction	−7,002,824
FY 2020 Estimated Total Burden Reduction	(4,224,173)

B. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, visit our website at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*, or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these information collection requirements. If you wish to comment, submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1714–P) and, where applicable, indicate the ICR's CFR citation, CMS ID number, and OMB control number.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule meets the requirements of our regulations at § 418.306(c) and (d), which require annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Core-Based Statistical Areas (CBSAs) or previously used Metropolitan Statistical Areas (MSAs), as well as any changes to the methodology for determining the per diem payment rates. This proposed rule would also update payment rates for each of the categories of hospice care, described in § 418.302(b), for FY 2020 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. Lastly, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this

rule discusses changes in the requirements for the hospice quality reporting program in accordance with section 1814(i)(5) of the Act.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this proposed rule would result in an estimated increase of $540 million in payments to hospices, resulting from the hospice payment update percentage of 2.7 percent for FY 2020. Section 1814(i)(6)(D)(ii) of the Act requires the proposed rebasing of the per diem payment rates for CHC, GIP, and IRC to be done in a budget-neutral manner in the first year of implementation. Therefore, the proposed rebased rates for CHC, GIP, and IRC would not result in an overall payment impact for the Medicare program as we are proposing to reduce the RHC payment rates to ensure that total estimated payments to hospices are budget-neutral given the proposed increases to the CHC, GIP, and IRC payment rates. In addition, the proposed change in the hospice wage index to use the FY 2020 pre-floor, pre-reclassified hospital wage index (rather than the FY 2019 pre-floor, pre-reclassified hospital wage index) as the basis for the FY 2020 hospice wage index would not result in an overall payment impact for the Medicare program as annual wage index updates are now similarly implemented in a budget-neutral manner. Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than $7.5 million to $38.5 million in any 1 year), or being nonprofit organizations. For purposes of the RFA, we consider all hospices as small entities as that term is used in the RFA. HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the FY 2020 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.7 percent, or $540 million. The distributional effects of the proposed FY 2020 hospice wage index do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Finally, the distributional effects of the proposed FY 2020 increases to the CHC, IRC, and GIP per diem payment rates as a result of rebasing, offset by a proposed decrease to the FY 2020 RHC payment rates of less than 3 percent to maintain budget neutrality in the first year of implementation, do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Therefore, the Secretary has determined that this rule will not create a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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 will only affect hospices. Therefore, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. The 2019 UMRA threshold is $154 million. This rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

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. We have reviewed this rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the

cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). This proposed rule consists of approximately 43,000 words. Assuming an average reading speed of 250 words per minute, it would take approximately one and a half hour for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is $153.55 (1.43 hour × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $18,733.10 ($153.55 × 122 reviewers).

D. Detailed Economic Analysis

1. Hospice Payment Update for FY 2020

The FY 2020 hospice payment impacts appear in table 24. We tabulate the resulting payments according to the classifications (for example, provider type, geographic region, facility size), and compare the difference between current and future payments to determine the overall impact. The first column shows the breakdown of all hospices by provider type and control (non-profit, for-profit, government, other), facility location, facility size. The second column shows the number of hospices in each of the categories in the first column. The third column shows our estimate of applying the proposed rebased payment rates of CHC, IRC, and GIP (and the decreased RHC rate used to achieve budget neutrality). The fourth column shows the hospice payments using FY 2018 Hospice Claims, FY 2020 rebased Payments, and FY 2020 Wage Index without the 1-Year lag. The fifth column show the proposed FY 2020 hospice payment update percentage of 2.7 percent as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The 2.7 percent hospice payment update percentage is based on an estimated 3.2 percent inpatient hospital market basket update, reduced by a 0.5 percentage point productivity adjustment. It is projected that aggregate payments would increase by 2.7 percent, assuming hospices do not change their service and billing practices. The sixth column shows the estimated total impact for FY 2020. We have set the rates so the overall impact is zero percent due to the requirement that any revisions in payment are implemented in a budget-neutral manner in accordance with section 1814(i)(6)(D)(ii) of the Act (accomplished for the proposed rebasing of the CHC, GIP, and IRC payment rates by a corresponding proposed decrease to the RHC payment rates).

In addition, to assist providers in understanding the potential impacts of the proposed wage index with and without the lag and the proposed rebasing of CHC, IRC, and GIP, we are providing a provider-specific impact analysis file, which is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Regulations-and-Notices.html.* We note that simulated payments are based on utilization in FY 2018 as seen on Medicare hospice claims (accessed from the CCW in January of 2019) and only include payments related to the level of care and do not include payments related to the service intensity add-on.

As illustrated in table 25, the combined effects of all the proposals vary by specific types of providers and by location.

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Table 25: Projected Impact to Hospices for FY 2020

	Hospices	Proposed Rebasing of CHC, IRC, and GIP	FY 2020 Updated Wage Data Without the 1 Year Lag	Proposed FY 2020 Hospice Payment Update Percentage	Estimated Total Impact for FY 2020
All Hospices	4,569	0.0%	0.0%	2.7%	2.7%
Hospice Type and Control					
Freestanding/Non-Profit	601	1.4%	0.1%	2.7%	4.2%
Freestanding/For-Profit	2,819	-0.8%	-0.1%	2.7%	1.8%
Freestanding/Government	39	0.0%	-0.3%	2.7%	2.4%
Freestanding/Other	322	0.2%	0.1%	2.7%	3.0%
Provider/HHA-Based/Non-Profit	396	0.7%	0.0%	2.7%	3.4%
Provider/HHA-Based/For-Profit	194	-1.3%	0.0%	2.7%	1.4%
Provider/HHA-Based/Government	101	0.4%	0.2%	2.7%	3.3%
Provider/HHA-Based/Other	97	0.6%	0.0%	2.7%	3.3%
Subtotal: Freestanding Provider Type	3,781	0.0%	0.0%	2.7%	2.7%
Subtotal: Provider/HHA Based Provider Type	788	0.2%	0.0%	2.7%	2.9%
Subtotal: Non-Profit	997	1.3%	0.1%	2.7%	4.1%
Subtotal: For Profit	3,013	-0.8%	-0.1%	2.7%	1.8%
Subtotal: Government	140	0.2%	-0.1%	2.7%	2.8%
Subtotal: Other	419	0.3%	0.1%	2.7%	3.1%
Hospice Type and Control: Rural					
Freestanding/Non-Profit	154	0.4%	0.5%	2.7%	3.6%
Freestanding/For-Profit	328	-1.7%	0.2%	2.7%	1.2%
Freestanding/Government	20	-0.8%	0.0%	2.7%	1.9%
Freestanding/Other	45	-1.3%	0.2%	2.7%	1.6%
Provider/HHA-Based/Non-Profit	157	0.6%	0.0%	2.7%	3.3%
Provider/HHA-Based/For-Profit	47	-1.6%	0.1%	2.7%	1.2%
Provider/HHA-Based/Government	74	-0.7%	0.3%	2.7%	2.3%
Provider/HHA-Based/Other	54	-0.5%	0.5%	2.7%	2.7%
Hospice Type and Control: Urban					
Freestanding/Non-Profit	447	1.5%	0.1%	2.7%	4.3%
Freestanding/For-Profit	2,491	-0.7%	-0.1%	2.7%	1.9%
Freestanding/Government	19	0.1%	-0.3%	2.7%	2.5%
Freestanding/Other	277	0.3%	0.1%	2.7%	3.1%
Provider/HHA-Based/Non-Profit	239	0.7%	0.0%	2.7%	3.4%
Provider/HHA-Based/For-Profit	147	-1.3%	0.0%	2.7%	1.4%
Provider/HHA-Based/Government	27	1.4%	0.1%	2.7%	4.2%

Provider/HHA-Based/Other	43	0.9%	-0.1%	2.7%	3.5%
Hospice Location: Urban or Rural					
Rural	879	-0.8%	0.2%	2.7%	2.1%
Urban	3,690	0.1%	0.0%	2.7%	2.8%
Hospice Location: Region of the Country (Census Division)					
New England	157	0.0%	-0.5%	2.7%	2.2%
Middle Atlantic	281	0.2%	-0.1%	2.7%	2.8%
South Atlantic	554	2.0%	0.0%	2.7%	4.7%
East North Central	543	0.1%	0.0%	2.7%	2.8%
East South Central	263	-0.4%	0.1%	2.7%	2.4%
West North Central	404	-1.4%	0.6%	2.7%	1.9%
West South Central	875	-0.5%	0.1%	2.7%	2.3%
Mountain	458	-0.6%	0.2%	2.7%	2.3%
Pacific	988	-1.5%	-0.2%	2.7%	1.0%
Outlying	46	-2.7%	-0.3%	2.7%	-0.3%
Hospice Size					
0 - 3,499 RHC Days (Small)	971	-1.0%	0.0%	2.7%	1.7%
3,500-19,999 RHC Days (Medium)	2,130	-1.1%	0.0%	2.7%	1.6%
20,000+ RHC Days (Large)	1,468	0.3%	0.0%	2.7%	3.0%

Source: FY 2018 hospice claims data as of December 31, 2018 from the CCW RIFs, accessed January 2019.

Region Key:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**= Alaska, California, Hawaii, Oregon, Washington
Outlying=Guam, Puerto Rico, Virgin Islands

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2. Proposed Hospice Election Statement Addendum

This proposed rule includes proposals related to the election statement addendum that would be provided, upon request, to hospice beneficiaries (or representative), non-hospice providers, and Medicare contractors. If finalized, this change would become effective for hospice elections on and after October 1, 2019. The election statement addendum would add no additional burden for communicating with non-hospice providers, as this decision-making process has been a long-standing CoP requirement, as described in the preamble of this proposed rule. However, burden would be reduced for non-hospice providers, including institutional, non-institutional and pharmacy providers because less time would be spent trying to obtain needed information for treatment decisions and accurate claims submissions. As a result of this election statement addendum, we estimate that this rule generates $4.2 million in annualized cost savings, or $3 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2020. The burden reduction for this proposal is detailed in section IV of this proposed rule and the total annual reduction is included in table 24.

E. Alternatives Considered

For the FY 2020 Hospice Wage Index and Rate Update proposed rule, we considered alternatives to the proposals articulated in section III.A. First, we considered not applying the Level I edits to the freestanding cost reports to estimate the FY 2017 costs per day by level of care. Our analysis showed that the differences in costs for each level of care between these two approaches were minimal. As described in the FY 2019 hospice proposed rule (89 FR 20949), industry representatives have suggested using these Level I edits to force adherence to certain cost reporting principles that could lead to the reporting of higher-quality hospice cost data and therefore, we believe it is most technically appropriate to apply the Level I edits. Table 26 describes the FY 2017 estimated, average per day costs by level of care applying all cost report adjustments, and those same estimated costs applying all cost report adjustments except the Level I edits.

TABLE 26—FREESTANDING HOSPICE AVERAGE PER DAY COSTS WITHOUT LEVEL I EDITS, FY 2017

Level of care	Estimated average cost per day using all adjustments	Estimated average cost per day using all adjustments, except Level I edits
RHC (Days 1–60)	$164.89	$164.17.
RHC (Days 61+)	$114.11	$113.62.
CHC	$54.49 ($1,307.76 for 24 hours)	$53.83 ($1,291.92 for 24 hours).
IRC	$438.97	$467.78.
GIP	$953.95	$960.12.

We also considered proposing to use freestanding and provider-based cost reports to rebase CHC, IRC, and GIP per diem rates, rather than using only freestanding hospice cost reports. When we analyzed both freestanding and provider-based cost reports, the results from these two samples tend to be similar, however, on average, incorporating provider-based cost reports results in higher costs than the cost reports for freestanding hospices only as shown in table 27.

TABLE 27—FREESTANDING AND PROVIDER-BASED AVERAGE COST PER DAY BY LEVEL OF CARE, FY 2017

Level of care	Freestanding average cost per day	Provider-based average cost per day
RHC (Days 1–60)	$164.89	$169.36.
RHC (Days 61+)	$114.11	$117.21.
CHC	$54.49 ($1,307.76 for 24 hours)	$56.20 ($1,348.80 for 24 hours).
IRC	$438.98	$521.74.
GIP	$953.96	$956.04.

—With all cost report adjustments applied.
—With Level I Edits.

Since the costs are higher, the FY 2019 rebased payment rates for CHC, GIP, and IRC when using cost reports for both freestanding and provider-based hospices would also be higher and we would need to reduce the RHC payment more in order to maintain budget neutrality as shown in table 28. If we utilized freestanding and provider-based cost reports, RHC would need to be reduced by 2.92 percent to offset the increases to the per diem payment amounts for CHC, GIP, and IRC.[49]

TABLE 28—REBASED PAYMENT RATES FOR CHC, IRC, AND GIP LEVELS OF CARE USING FREESTANDING AND PROVIDER-BASED HOSPICE COST REPORTS, FY 2019

Level of care	Rebased payment rates
Continuous Home Care (CHC)	$58.59 per hour/$1,406.04 (per day).
Inpatient Respite Care (IRC)	$517.98.*
General Inpatient Care (GIP)	$996.62.

Note:
—Prior to application of the hospice payment update percentage of 2.7 percent outlined in section III.B.4 of this proposed rule.
—Includes Level I edits.
* IRC payment rate accounts for 5 percent coinsurance ($543.88 / 1.05 = $517.98).

In MedPAC's March 2018 Report to Congress, MedPAC stated that included in the costs of provider-based hospices are overhead costs allocated from the parent provider, which contributes to provider-based hospices having higher costs than freestanding providers. The Commission believes payment policy should focus on the efficient delivery of services to Medicare's beneficiaries. If freestanding hospices are able to provide high-quality care at a lower cost than provider-based hospices, payment rates should be set accordingly, and the higher costs of provider-based hospices should not be a reason for increasing Medicare payment rates.[50] Similarly, the application of the cost report exclusions yielded a small sample size of provider-based cost reports and when we applied the Level I cost report edits to the provider-based cost reports, this trimmed out nearly all of the provider-based cost reports. Therefore, we are less confident in the calculations of the average costs per day by level of care using provider-based hospice cost reports as very few of such providers had costs reports that were not trimmed out due to the recently implemented Level I cost report edits. We invite comments on the alternatives considered discussed in this analysis.

F. Accounting Statement

As required by OMB Circular A–4 (available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in table 29, we have prepared an accounting statement showing the classification of the transfers and costs

[49] Using the average per-diem costs generated from our sample of freestanding and provider-based hospice cost reports, rebasing CHC, IRC, and GIP results in extra payments of $503,162,283.48 for those levels of care. The RHC payments that were made under the payment rates in place during FY 2019 were $17,218,209,794.15. One minus the value of the extra payments over the RHC payments equals 0.9708.

[50] Medicare Payment Advisory Commission (MedPAC). ''Hospice Services.'' *Report to the Congress: Medicare Payment Policy.* Washington, DC. March 2018. P. 341. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch12_sec.pdf?sfvrsn=0.*

associated with the provisions of this proposed rule. This table shows an estimated $540 million in transfers to hospices in FY 2020. All expenditures are classified as transfers to hospices. Table 29 also reflects the estimated change in costs and burden for hospices and non-hospice providers as a result of the proposed election statement addendum requirements described in section III.C. Table 29 provides our best estimate of a one-time burden for hospices to develop the election statement addendum form of 2,233 hours or $196,281, as well as our estimate of the annual burden for hospices to complete the election statement addendum of 744 hours or $12.6 million for an estimated total burden for hospices of $12.8 million, as described in section IV of this proposed rule. Additionally, we estimate a net reduction in burden for non-hospice providers of 25,866 hours or $17 million (see section IV of this proposed rule) for an estimated overall, annualized net reduction in burden with the proposed election statement addendum of $4.2 million.

TABLE 29—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FY 2019 TO FY 2020

Category	Transfers
Annualized Monetized Transfers	$ 540 million.*
From Whom to Whom?	Federal Government to Medicare Hospices.
Category	**Costs**
Annualized Monetized Net Reduction in Burden for Non-Hospice Providers with the Proposed Regulations Change at § 418.24, Election Statement Addendum.	−$17.0 million.
Annualized Net Burden for Hospice Providers with the One-time Form Development and Completion of Election Statement Addendum.	+$12.8 million.
Total Annualized Net Reduction In Burden with the Proposed Election Statement Addendum	−$4.2 million.

*The net increase of $540 million in transfer payments is a result of the 2.7 percent hospice payment update compared to payments in FY 2019.

G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017) and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is expected to be an E.O. 13771 deregulatory action with $4.2 million in annualized cost savings, or $3 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in FY 2020. The burden reduction for this proposal is detailed in section IV of this proposed rule and the total annual reduction is included in Table 24. Details on the estimated cost savings of this rule with comment period can be found in the rule's collection of information and economic analysis.

H. Conclusion

We estimate that aggregate payments to hospices in FY 2020 will increase by $540 million, or 2.7 percent, compared to payments in FY 2019. We estimate that in FY 2020, hospices in urban and rural areas will experience, on average, 2.8 percent and 2.1 percent increases, respectively, in estimated payments compared to FY 2019. Hospices providing services in the South Atlantic, Middle Atlantic and East North Central regions would experience the largest estimated increases in payments of 4.7 percent and 2.8 percent, respectively. Hospices serving patients in the Pacific and outlying regions would experience, on average, the lowest estimated increase of 1.0 and −0.3 percent, respectively in FY 2020 payments. We also estimate an overall reduction in burden of $4.2 million as a result of the proposed election statement addendum. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 418–HOSPICE CARE

■ 1. The authority citation for part 418 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 418.24 is amended by—
■ a. Revising paragraphs (b)(2) and (3);
■ b. Redesignating paragraph (b)(5) as paragraph (b)(8);
■ c. Adding new paragraphs (b)(5), (6), and (7);
■ d. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g), respectively; and
■ e. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 418.24 Election of hospice care.

* * * * *

(b) * * *

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions.

(3) Acknowledgement that the individual has been provided information on the hospice's coverage responsibility and that certain Medicare services, as set forth in paragraph (e) of this section, are waived by the election. This includes providing the individual with information indicating that services unrelated to the terminal illness and related conditions are exceptional and unusual and hospice should be providing virtually all care needed by the individual who has elected hospice.

* * * * *

(5) Information on individual cost-sharing for hospice services.

(6) Notification of the individual's (or representative's) right to receive an election statement addendum, as set forth in paragraph (c) of this section, if there are conditions, items, services, and drugs the hospice has determined to be unrelated to the individual's terminal illness and related conditions and would not be covered by the hospice.

(7) Information on BFCC–QIO, including the right to immediate advocacy and BFCC–QIO contact information.

* * * * *

(c) *Content of hospice election statement addendum.* In the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement. If the election statement addendum is requested at the time of hospice election, the hospice must provide this information, in writing, to the individual (or representative) within 48 hours. If this addendum is requested during the course of the hospice election, the hospice must provide this information, in writing, immediately to the requesting individual (or representative), non-hospice provider, or Medicare contractor. If there are any changes to the content on the addendum during the course of the hospice election, the hospice must update the addendum and provide these updates, in writing, to the individual (or representative). The election statement addendum must include the following:

(1) The addendum must be titled ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs.''

(2) Name of the hospice.

(3) Individual's name and hospice medical record identifier.

(4) Identification of the individual's terminal illness and related conditions.

(5) A list of the individual's conditions present on hospice admission (or upon plan of care update) and the associated items, services, and drugs not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions.

(6) A written clinical explanation, in language the individual (or representative) can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the individual's terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs unrelated to their terminal illness and related conditions.

(7) References to any relevant clinical practice, policy, or coverage guidelines.

(8) Information on the following—

(i) *Purpose of addendum.* The purpose of the addendum is to notify the individual (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions.

(ii) *Right to immediate advocacy.* The addendum must include language that immediate advocacy is available through the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC–QIO) if the individual (or representative) disagrees with the hospice's determination.

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the individual's (or representative's) agreement with the hospice's determinations.

* * * * *

Dated: April 4, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 9, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–08143 Filed 4–19–19; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413
Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413

[CMS–1718–P]

RIN 0938–AT75

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2020. We also propose minor revisions to the regulation text to reflect the revised assessment schedule under Patient Driven Payment Model (PDPM). Additionally, we propose to revise the definition of group therapy under the SNF PPS, and to implement a subregulatory process for updating the code lists (International Classification of Diseases, Tenth Version (ICD–10) codes) used under PDPM. We are also soliciting comments on stakeholder concerns regarding the appropriateness of the wage index used to adjust SNF payments. In addition, the proposed rule includes proposals for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program that will affect Medicare payment to SNFs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 18, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1718–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1718–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1718–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

Anthony Hodge, (410) 786–6645, for information related to payment for SNF-level swing-bed services.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes, and general information.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations and consolidated billing.

Casey Freeman, (410) 786–4354, for information related to skilled nursing facility quality reporting program.

James Poyer, (410) 786–2261, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this proposed rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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I. Executive Summary

A. Purpose

This proposed rule would update the SNF prospective payment rates for fiscal year (FY) 2020 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It would also respond to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register**, before the August 1 that precedes the start of each FY, certain specified information relating to the payment update (see section II.C. of this proposed rule). This proposed rule also proposes to revise the definition of group therapy under the SNF PPS and to implement a subregulatory process for updating ICD–10 code lists used under the PDPM.

Finally, this proposed rule would also update the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP).

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this proposed rule would reflect an update to the rates that we published in the SNF PPS final rule for FY 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832), which reflects the SNF market basket update, as adjusted by the multifactor productivity (MFP) adjustment, for FY 2020. In addition, we are proposing to revise the definition of group therapy under the SNF PPS and to implement a subregulatory process for updating ICD–10 code lists used under the PDPM.

This proposed rule proposes to update requirements for the SNF QRP, including the proposal of two Transfer of Health Information quality measures as well as standardized patient assessment data elements to begin collection on October 1, 2020 in satisfaction of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted October 6, 2014). We are also proposing to exclude baseline nursing home residents from the Discharge to Community Measure. In addition, we are proposing to expand data collection for SNF QRP quality measures to all skilled nursing facility residents, regardless of their payer. Further, we are also proposing the public display of the quality measure, Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP). We are also proposing to revise references in regulation text to reflect enhancements to the system used for the submission of data. Finally, we are requesting information on quality measures and standardized resident assessment data elements under consideration for future years.

In accordance with section 1888(h) of the Act, this proposed rule would update certain policies for the SNF VBP.

C. Summary of Cost and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total transfers
FY 2020 SNF PPS payment rate update	The overall economic impact of this proposed rule is an estimated increase of $887 million in aggregate payments to SNFs during FY 2020.
FY 2020 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $213.6 million in aggregate payments to SNFs during FY 2020.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in post-acute care, we developed a Data Element Library (DEL) to serve as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability, which is also a goal of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 ISA is available at *https://www.healthit.gov/isa*.

The 21st Century Cures Act (the Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. In another important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. In March 2019, ONC and CMS published the proposed rules, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,'' (84 FR 7424) and ''Interoperability and Patient Access'' (84 FR 7610) to promote secure and more immediate access to health information for patients and healthcare providers through the implementation of information blocking provisions of the Cures Act and the use of standardized application programming interfaces (APIs) that enable easier access to electronic health information. These two proposed rules are open for public comment at *www.regulations.gov*. We invite providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted on August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998

interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act amended section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs under which SNFs report data on measures and resident assessment data.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this proposed rule will provide the required annual updates to the per diem payment rates for SNFs for FY 2020.

III. Proposed SNF PPS Rate Setting Methodology and FY 2020 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we revised and rebased the market basket index, which included updating the base year from FY 2010 to 2014.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.4. of this proposed rule. For FY 2020, the growth rate of the 2014-based SNF market basket is estimated to be 3.0 percent, based on the IHS Global Insight, Inc. (IGI) first quarter 2019 forecast with historical data through fourth quarter 2018, before the multifactor productivity adjustment is applied.

In section III.B.5. of this proposed rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

2. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this proposed rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2020. This factor is based on the FY 2020 percentage increase in the 2014-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. In this proposed rule, the SNF market basket percentage is estimated to be 3.0 percent for FY 2020 based on IGI's first quarter 2019 forecast (with historical data through fourth quarter 2018). Finally, as discussed in section II.B. of this proposed rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2018 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.6 percentage points, and the actual increase for FY 2018 is 2.6 percentage points, resulting in the actual increase being the same as the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 3.0 percent would not be adjusted to account for the forecast error correction. Table 2 shows the forecasted and actual market basket amounts for FY 2018.

TABLE 2—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2018

Index	Forecasted FY 2018 increase *	Actual FY 2018 increase **	FY 2018 difference
SNF	2.6	2.6	0.0

* Published in **Federal Register**; based on second quarter 2017 IGI forecast (2010-based index).
** Based on the first quarter 2019 IGI forecast, with historical data through the fourth quarter 2018 (2010-based index).

4. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the multifactor productivity (MFP) adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

a. Incorporating the MFP Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

The MFP adjustment, calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2020, is estimated to be 0.5 percent based on IGI's first quarter 2019 forecast. Also, consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), the market basket percentage for FY 2020 for the SNF PPS is based on IGI's first quarter 2019 forecast of the SNF market basket percentage, which is estimated to be 3.0 percent. In accordance with section 1888(e)(5)(B)(ii) of the Act and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment of 0.5 percent. The resulting MFP-adjusted SNF market basket update would be equal to 2.5 percent, or 3.0 percent less 0.5 percentage point.

5. Market Basket Update Factor for FY 2020

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2020 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2018, through September 30, 2019 to the average market basket level for the period of October 1, 2019, through September 30, 2020. This process yields a percentage change in the 2014-based SNF market basket of 3.0 percent. As further explained in section III.B.3. of this proposed rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the difference between the forecasted FY 2018 SNF market basket percentage change and the actual FY 2018 SNF market basket percentage change (FY 2018 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 3.0 percent would not be adjusted by the forecast error correction.

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (10-year moving average of changes in MFP for the period ending September 30, 2020) of 0.5 percent, as described in section III.B.4 of this proposed rule. The resulting net SNF market basket update would equal 2.5 percent, or 3.0 percent less the 0.5 percentage point MFP adjustment. We note that our policy has been that, if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than 0.0 for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only with respect to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

Accordingly, for the reasons specified in this proposed rule, we are proposing to apply the FY 2020 SNF market basket increase factor of 2.5 percent in our determination of the FY 2020 SNF PPS unadjusted federal per diem rates, which reflects a market basket increase factor of 3.0 percent, less the 0.5 percentage point MFP-adjustment.

6. Unadjusted Federal per Diem Rates for FY 2020

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), we are implementing a new case-mix classification system to classify SNF patients under the SNF PPS, beginning in FY 2020, called the Patient Driven Payment Model (PDPM). As discussed in section V.B of that final rule, under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as exists under RUG–IV. In calculating the FY 2020 unadjusted Federal per diem rates that would be used under PDPM in FY 2020, we applied the FY 2020 MFP-adjusted market basket increase factor to the unadjusted Federal per diem rates provided in Tables 4 and 5 of the FY 2019 SNF PPS final rule (83 FR 39169) and then applied the methodology for separating the RUG–IV base rates into the PDPM base rates, as discussed and finalized in section V.B.3 of the FY 2019 SNF PPS final rule (83 FR 39191 through 39194).

Tables 3 and 4 reflect the proposed updated unadjusted federal rates for FY 2020, prior to adjustment for case-mix.

TABLE 3—FY 2020 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$61.16	$56.93	$22.83	$106.64	$80.45	$95.48

TABLE 4—FY 2020 UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$69.72	$64.03	$28.76	$101.88	$76.86	$97.25

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, to take effect beginning October 1, 2019. The RUG–IV model classifies most patients into a therapy payment group and primarily uses the volume of therapy services provided to the patient as the basis for payment classification, thus inadvertently creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM (like the RUG–IV) uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS. As discussed in section IV.A. of this proposed rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H), each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2020 payment rates set forth in this proposed rule reflect the use of the PDPM case-mix classification system from October 1, 2019, through September 30, 2020. We list the proposed case-mix adjusted PDPM payment rates for FY 2020, provided separately for urban and rural SNFs, in Tables 6 and 7 with corresponding case-mix values.

As discussed in the FY 2019 SNF PPS final rule (83 FR 39255 through 39256), we finalized the implementation of PDPM in a budget neutral manner. To accomplish this, as discussed in the FY 2019 SNF PPS final rule (83 FR 39256), the unadjusted PDPM case mix indexes (CMIs) were multiplied by 1.46 so that the total estimated payments under the PDPM would be equal to the total actual payments under RUG–IV. Further, section 3.11.2 of the PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/PDPM_Technical_Report_508.pdf,* provided additional detail on the calculation of the PDPM CMIs in order to achieve budget neutrality. In that section, it states that ''to align the distribution of resources across components with the statutory base rates, Acumen set CMIs such that the average product of the CMI and the variable per diem adjustment factor for a day of care is the same (set to 1) for each of the five case-mix-adjusted components in PDPM. To do this, Acumen first calculated the product of the CMI and the adjustment factor for every utilization day for each component. Then, we calculated the average of this product for each component. Finally, Acumen calculated the ratio of 1 divided by the average product for each component. This ratio is the standardization multiplier, shown in Table 65 for each component.'' As discussed in section 3.11.2 of the PDPM Technical Report, the standardization multiplier is used to align the distribution of resources across components with the statutory base rates by setting the CMIs such that the average product of the component CMI and the variable per diem adjustment factor for that component for a day of care is the same. Effectively, the standardization multiplier is used to mitigate the effect of the variable per diem adjustment when calculating budget neutrality. The CMIs were adjusted such that total payments under PDPM, if it had been in effect in FY 2017, equal total actual payments made under RUG–IV in FY 2017.

In this proposed rule, we propose to update the payment year used as the basis for the calculation of the standardization multiplier and budget neutrality multiplier, in order to best ensure that PDPM will be implemented in a budget neutral manner, as finalized in the FY 2019 SNF PPS final rule. The only difference in methodology between that used to calculate these multipliers and CMIs in the FY 2019 SNF PPS final rule and that used to calculate the multipliers and CMIs in this proposed rule is that, in this proposed rule, we are updating the data used from FY 2017 data to FY 2018 data. The impact of using the updated FY 2018 data and the proposed updated adjustment multipliers for standardization and budget neutrality, is provided in Table 5. We would note that while the multipliers discussed in the FY 2019 SNF PPS final rule and in the PDPM Technical Report are given to the hundredths place, in order to make clear the effect of this change in data, the multipliers in Table 5 are shown to the thousandths place. The CMIs provided in Tables 6 and 7 reflect the use of the proposed multipliers in Table 5, based on the update to FY 2018 data.

TABLE 5—PROPOSED PDPM STANDARDIZATION AND BUDGET NEUTRALITY MULTIPLIERS

Component	FY 2017 data		FY 2018 data	
	Standardization multiplier	Budget neutrality multiplier	Standardization multiplier	Budget neutrality multiplier
PT	1.031	1.458	1.028	1.463
OT	1.030	1.458	1.028	1.463
SLP	0.995	1.458	0.996	1.463
Nursing	0.995	1.458	0.996	1.463
NTA	0.817	1.458	0.811	1.463

Given the differences between RUG–IV and PDPM in terms of patient classification and billing, it is important that the format of Tables 6 and 7 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim in order to bill for covered SNF services. Under RUG–IV, the HIPPS code includes the three character RUG–IV group into which the patient classifies as well as a two character assessment indicator code that represents the assessment used to generate this code. Under PDPM, while providers would still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Therefore, we have modified the format of Tables 6 and 7 from what we have used for similar tables in prior SNF PPS rulemaking, such as Tables 6 and 7 of the FY 2019 SNF PPS final rule (83 FR 39170 through 39172). Column 1 of Tables 6 and 7 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group. Tables 6 and 7 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section VI.B. of this proposed rule, or the SNF VBP program, discussed in sections III.B.5. and VI.C. of this proposed rule, or other adjustments, such as the variable per diem adjustment. Further, we use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility.

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TABLE 6: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes--URBAN

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	$93.57	1.49	$84.83	0.68	$15.52	ES3	4.06	$432.96	3.24	$260.66
B	1.70	$103.97	1.63	$92.80	1.82	$41.55	ES2	3.07	$327.38	2.53	$203.54
C	1.88	$114.98	1.69	$96.21	2.67	$60.96	ES1	2.93	$312.46	1.84	$148.03
D	1.92	$117.43	1.53	$87.10	1.46	$33.33	HDE2	2.40	$255.94	1.33	$107.00
E	1.42	$86.85	1.41	$80.27	2.34	$53.42	HDE1	1.99	$212.21	0.96	$77.23
F	1.61	$98.47	1.60	$91.09	2.98	$68.03	HBC2	2.24	$238.87	0.72	$57.92
G	1.67	$102.14	1.64	$93.37	2.04	$46.57	HBC1	1.86	$198.35	-	-
H	1.16	$70.95	1.15	$65.47	2.86	$65.29	LDE2	2.08	$221.81	-	-
I	1.13	$69.11	1.18	$67.18	3.53	$80.59	LDE1	1.73	$184.49	-	-
J	1.42	$86.85	1.45	$82.55	2.99	$68.26	LBC2	1.72	$183.42	-	-
K	1.52	$92.96	1.54	$87.67	3.70	$84.47	LBC1	1.43	$152.50	-	-
L	1.09	$66.66	1.11	$63.19	4.21	$96.11	CDE2	1.87	$199.42	-	-
M	1.27	$77.67	1.30	$74.01	-	-	CDE1	1.62	$172.76	-	-
N	1.48	$90.52	1.50	$85.40	-	-	CBC2	1.55	$165.29	-	-
O	1.55	$94.80	1.55	$88.24	-	-	CA2	1.09	$116.24	-	-
P	1.08	$66.05	1.09	$62.05	-	-	CBC1	1.34	$142.90	-	-
Q	-	-	-	-	-	-	CA1	0.94	$100.24	-	-
R	-	-	-	-	-	-	BAB2	1.04	$110.91	-	-
S	-	-	-	-	-	-	BAB1	0.99	$105.57	-	-
T	-	-	-	-	-	-	PDE2	1.57	$167.42	-	-
U	-	-	-	-	-	-	PDE1	1.47	$156.76	-	-
V	-	-	-	-	-	-	PBC2	1.22	$130.10	-	-
W	-	-	-	-	-	-	PA2	0.71	$75.71	-	-
X	-	-	-	-	-	-	PBC1	1.13	$120.50	-	-
Y	-	-	-	-	-	-	PA1	0.66	$70.38	-	-

TABLE 7: RUG-IV Case-Mix Adjusted Federal Rates and Associated Indexes—RURAL

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	$106.67	1.49	$95.40	0.68	$19.56	ES3	4.06	$413.63	3.24	$249.03
B	1.70	$118.52	1.63	$104.37	1.82	$52.34	ES2	3.07	$312.77	2.53	$194.46
C	1.88	$131.07	1.69	$108.21	2.67	$76.79	ES1	2.93	$298.51	1.84	$141.42
D	1.92	$133.86	1.53	$97.97	1.46	$41.99	HDE2	2.40	$244.51	1.33	$102.22
E	1.42	$99.00	1.41	$90.28	2.34	$67.30	HDE1	1.99	$202.74	0.96	$73.79
F	1.61	$112.25	1.60	$102.45	2.98	$85.70	HBC2	2.24	$228.21	0.72	$55.34
G	1.67	$116.43	1.64	$105.01	2.04	$58.67	HBC1	1.86	$189.50	-	-
H	1.16	$80.88	1.15	$73.63	2.86	$82.25	LDE2	2.08	$211.91	-	-
I	1.13	$78.78	1.18	$75.56	3.53	$101.52	LDE1	1.73	$176.25	-	-
J	1.42	$99.00	1.45	$92.84	2.99	$85.99	LBC2	1.72	$175.23	-	-
K	1.52	$105.97	1.54	$98.61	3.70	$106.41	LBC1	1.43	$145.69	-	-
L	1.09	$75.99	1.11	$71.07	4.21	$121.08	CDE2	1.87	$190.52	-	-
M	1.27	$88.54	1.30	$83.24	-	-	CDE1	1.62	$165.05	-	-
N	1.48	$103.19	1.50	$96.05	-	-	CBC2	1.55	$157.91	-	-
O	1.55	$108.07	1.55	$99.25	-	-	CA2	1.09	$111.05	-	-
P	1.08	$75.30	1.09	$69.79	-	-	CBC1	1.34	$136.52	-	-
Q	-	-	-	-	-	-	CA1	0.94	$95.77	-	-
R	-	-	-	-	-	-	BAB2	1.04	$105.96	-	-
S	-	-	-	-	-	-	BAB1	0.99	$100.86	-	-
T	-	-	-	-	-	-	PDE2	1.57	$159.95	-	-
U	-	-	-	-	-	-	PDE1	1.47	$149.76	-	-
V	-	-	-	-	-	-	PBC2	1.22	$124.29	-	-
W	-	-	-	-	-	-	PA2	0.71	$72.33	-	-
X	-	-	-	-	-	-	PBC1	1.13	$115.12	-	-
Y	-	-	-	-	-	-	PA1	0.66	$67.24	-	-

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D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We propose to continue this practice for FY 2020, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, unadjusted for occupational mix and the rural floor, as the basis for the SNF PPS wage index. For FY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (FY 2016 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted on December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. As discussed in greater detail later in this section, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not regard an undertaking of this magnitude as being feasible within the current level of programmatic resources.

In addition, we propose to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the

FY 2019 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2020, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2020, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The final wage index applicable to FY 2020 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300). As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we wish to note that this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index.

Once calculated, we would apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2020. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2020 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2020 in four steps. First, we compute the FY 2020 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2020 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2020 relative importance for each cost category by multiplying this ratio by the base year (2014) weight. Finally, we add the FY 2020 relative importance for each of the labor-related cost categories (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related services, and a portion of Capital-Related expenses) to produce the FY 2020 labor-related relative importance. Table 8 summarizes the proposed labor-related share for FY 2020, based on IGI's first quarter 2019 forecast with historical data through fourth quarter 2018, compared to the labor-related share that was used for the FY 2019 SNF PPS final rule.

TABLE 8—LABOR-RELATED RELATIVE IMPORTANCE, FY 2019 AND FY 2020

	Relative importance, labor-related, FY 2019 18:2 forecast [1]	Relative importance, labor-related, FY 2020 19:1 forecast [2]
Wages and salaries	50.2	50.6
Employee benefits	10.1	10.0
Professional Fees: Labor-Related	3.7	3.7
Administrative and facilities support services	0.5	0.5
Installation, Maintenance and Repair Services	0.6	0.6
All Other: Labor Related Services	2.5	2.5
Capital-related (.391)	2.9	2.9
Total	70.5	70.8

[1] Published in the **Federal Register**; based on second quarter 2018 IGI forecast.
[2] Based on first quarter 2019 IGI forecast, with historical data through fourth quarter 2018.

In order to calculate the labor portion of the case-mix adjusted per diem rate, one would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2020 labor-related share percentage provided in Table 8. The remaining portion of the rate would be the non-labor portion. In prior years, we have included tables which provide the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that have existed in prior rulemaking.

Therefore, to aid stakeholders in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a revised hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2020 (federal rates effective October 1, 2019), we would apply an adjustment to fulfill the budget neutrality requirement. We would meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2019 to the weighted average wage adjustment factor for FY 2020. For this calculation, we would use the same FY 2018 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The proposed budget neutrality factor for FY 2020 would be 1.0060.

E. Wage Index Comment Solicitation

As discussed above, historically, we have calculated the SNF PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the SNF PPS wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust SNF PPS payments and suggestions for possible updates and improvements to the geographic adjustment of SNF PPS payments.

F. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VI.B. of this proposed rule for a discussion of our proposals for the SNF VBP Program.

G. Adjusted Rate Computation Example

The following series of tables provides an example of how payment would be calculated during FY 2020 under PDPM for a hypothetical 30 day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 43524), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 9 shows the adjustments made to the federal per diem rates (prior to application of any adjustments under the SNF QRP and SNF VBP programs as discussed above) to compute the provider's case-mix adjusted per diem rate for FY 2020, based on the patient's PDPM classification, as well as how the VPD adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 10 shows the adjustments made to the case-mix adjusted per diem rate from Table 9 to account for the provider's wage index. The wage index used in this example is based on the FY 2020 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Finally, Table 11 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 11 also includes the variable per diem (VPD) adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 11, SNF XYZ's total PPS payment for this particular patient's stay would equal $19,992.80.

TABLE 9—PDPM CASE-MIX ADJUSTED RATE COMPUTATION EXAMPLE

[Per diem rate calculation]

Component	Component group	Component rate	VPD adjustment factor	VPD adjustment rate
PT	TN	$90.52	1.00	$90.52
OT	TN	85.40	1.00	85.40
SLP	SH	65.29		65.29
Nursing	CBC2	165.29		165.29
NTA	NC	148.03	3.00	444.09
Non-Case-Mix		95.48		95.48
Total PDPM Case-Mix Adj. Per Diem				946.07

TABLE 10—WAGE INDEX ADJUSTED RATE COMPUTATION EXAMPLE

[PDPM wage index adjustment calculation]

HIPPS code	PDPM case-mix adjusted per diem	Labor portion	Wage index	Wage index adjusted rate	Non-labor portion	Total case mix and wage index adj. rate
NHNC1	$946.07	$669.82	0.9757	$653.54	$276.25	$929.79

TABLE 11—ADJUSTED RATE COMPUTATION EXAMPLE

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage index adjusted per diem rate
1	3.0	1.0	$929.79
2	3.0	1.0	929.79
3	3.0	1.0	929.79
4	1.0	1.0	638.83
5	1.0	1.0	638.83
6	1.0	1.0	638.83
7	1.0	1.0	638.83
8	1.0	1.0	638.83
9	1.0	1.0	638.83
10	1.0	1.0	638.83
11	1.0	1.0	638.83
12	1.0	1.0	638.83
13	1.0	1.0	638.83
14	1.0	1.0	638.83
15	1.0	1.0	638.83
16	1.0	1.0	638.83
17	1.0	1.0	638.83
18	1.0	1.0	638.83
19	1.0	1.0	638.83
20	1.0	1.0	638.83
21	1.0	0.98	635.37
22	1.0	0.98	635.37
23	1.0	0.98	635.37
24	1.0	0.98	635.37
25	1.0	0.98	635.37
26	1.0	0.98	635.37
27	1.0	0.98	635.37
28	1.0	0.96	631.91
29	1.0	0.96	631.91
30	1.0	0.96	631.91
Total Payment			19,992.80

IV. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.C. of this proposed rule. This

approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, to one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. Under that discussion, we designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in § 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the 5-day Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to make changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the 5-day assessment. Finally, regarding the new set of case-mix classifiers designated under the PDPM for this purpose, we noted in the FY 2019 SNF PPS final rule (83 FR 39253, August 8, 2018) our intent ''. . . to review the new designations going forward and make further adjustments over time as we gain actual operating experience under the new classification model.'' Accordingly, to the extent that it may become evident in actual practice that these new criteria are not accurately performing their intended role (for example, by capturing cases that do not actually require an SNF level of care), we would propose appropriate adjustments to correct them.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113, enacted on November 29, 1999) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of the specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA is an attempt to exclude from the PPS certain services

and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: they must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791). In this proposed rule, we specifically invite public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified above. Commenters should identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2019). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment in order to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

V. Issues Relating to PDPM Implementation

A. Revised Group Therapy Definition

As set forth in the FY 2019 SNF PPS final rule (83 FR 39162), effective October 1, 2019 under the PDPM, patients will be classified into case-mix groups under each therapy component based on patient characteristics rather than using the volume of therapy services furnished to the patient as the basis for classification. Additionally, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39243), we finalized a combined limit on concurrent and group therapy furnished to a patient, specifically that, for each therapy discipline, no more than 25 percent of the therapy services furnished to a patient in a covered Medicare Part A stay may be in a group or concurrent setting. Given these policy changes relating to therapy classification and therapy provision under the PDPM, as well as recent efforts to increase standardization across PAC settings, we believed it was appropriate to evaluate other policies associated with therapy under PDPM to determine if other policies should be revised as well.

In the FY 2012 SNF PPS final rule (76 FR 48511 through 48517), we finalized changes relating to the definition of group therapy and payment of group therapy services, specifically to define group therapy as the practice of one therapist or therapy assistant treating four patients at the same time while the patients are performing either the same or similar activities. In the FY 2012 SNF PPS final rule (76 FR 48511), we noted that, using our STRIVE data as a baseline, we identified under RUG–IV two significant changes in provider behavior related to the provision of therapy services to Medicare beneficiaries in SNFs. First, we saw a major decrease in the amount of concurrent therapy (that is therapy provided to two patients by one therapist or therapy assistant doing *different* activities) performed in SNFs, the minutes for which are divided between the two concurrent therapy participants when determining the patient's appropriate RUG classification. At the same time, we found a significant increase in the amount of group therapy services, which were not subject to the allocation requirement. Given this increase in group therapy services, we expressed concern that the method for reporting group therapy on the MDS created an inappropriate payment incentive to perform the group therapy in place of individual therapy, because the method of reporting group therapy

time did not require allocation among patients.

As we stated in the FY 2012 SNF PPS final rule (76 FR 48511), because in group therapy, patients are performing similar activities, in contrast to concurrent therapy, group therapy gives patients the opportunity to benefit from each other's therapy regimen by observing and interacting with one another and applying the lessons learned from others to one's own therapy program in order to progress. At that time, we stated that large groups, such as those of five or more participants, can make it difficult for the participants to engage with one another over the course of the session. In addition, we have long believed that individual therapists could not adequately supervise large groups, and since the inception of the SNF PPS in July 1998, we have capped the number of residents at four. Furthermore, we believed that groups of fewer than four participants did not maximize the group therapy benefit for the participants. As we stated in the FY 2012 final rule (76 FR 48511), we believed that in groups of two or three participants, the opportunities for patients in the group to interact and learn from each other are significantly diminished given the small size of the group. Thus, we revised the definition of group therapy to require a group size for the SNF setting of exactly four patients, which we believed was the size that permits the therapy participants to derive the maximum benefit from the group therapy setting.

Since that time, we have monitored group therapy utilization and found that, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39238), group therapy represents a very small proportion of therapy provided to SNF patients. Further, as discussed in the FY 2019 SNF PPS final rule (83 FR 39240 through 39241), some commenters suggested that we revise the definition of group therapy to include two to six participants doing the same or similar activities, as this would better align with the Inpatient Rehabilitation Facility (IRF) setting and allow increased flexibility so that patients in smaller SNFs, presumably where a group of exactly four patients may be difficult to attain, could utilize and benefit from group therapy. In our response to these comments, in the FY 2019 SNF PPS final rule (83 FR 39241), we stated that we may consider changing the definition of group therapy in future rulemaking. In the past we stated our concern that a group that consisted of more than 4 participants would not allow for adequate supervision of each participant as well as cause difficulty for participants to engage with one another in the most effective way. Conversely, we maintained that a group of fewer than 4 participants would not allow for effective interaction to best achieve the goals of a group. For these reasons, we defined group therapy as exactly 4 participants. However, based on our review of the use of group therapy in the IRF and outpatient settings where the definition of group therapy is less restrictive than the current definition under the SNF PPS, we have found that therapists do seem capable of managing groups of various sizes. Based on this review, we believe therapists have the clinical judgment to determine whether groups of different sizes would clinically benefit their patients, which they should be able to demonstrate with adequate documentation. Patients can often benefit from the psycho-social aspect of groups, and in some situations, a group of six participants is not too large to provide that benefit to participants. For example, a cooking activity which will provide very functional therapy for patients planning to return home can be done in a group of six that will enhance the patient's psycho-social experience in the SNF. Alternatively, a group of 2–3 patients can be clinically useful for certain patients as well. For example, a group of 2–3 patients who have pragmatic language difficulties following a stroke or head injury could very well benefit from a small communication group to work on the social aspects of language together without the concern of distraction that a larger group might cause. Thus, while we continue to maintain minimal concerns that some groups may be either too small or too large to allow for effective interaction, we believe that the potential clinical benefits of various size groups outweigh our concerns, and that it would be appropriate to allow therapists greater flexibility to perform therapy in groups of different sizes.

In light of our discussion above and the comments in the FY 2019 SNF PPS final rule, and to align the SNF PPS more closely with other settings, in this proposed rule, we propose to adopt a new definition of group therapy for use under PDPM, effective October 1, 2019, as further discussed below.

In an effort to support CMS' cross-setting initiatives under the IMPACT Act and Meaningful Measures Initiative, we have looked at ways to align the definition of group therapy used under the SNF PPS more closely with the definitions used within the outpatient setting covered under Medicare Part B and under the IRF PPS, as this type of standardization would reduce administrative burden on providers by utilizing the same or similar definitions across settings. For group therapy in the outpatient setting, the Medicare Benefit Policy Manual, Chapter 15, Section 230 states that contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (CPT code 97150). This manual section further states that the individuals can be, but need not be, performing the same activity. In addition, this section states that the physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required. Under the IRF PPS, the definition of group therapy (found in Section 2 of the IRF PAI Training Manual, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip*) is the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) treating two to six patients at the same time who are performing the same or similar activities.

We considered using the same definition as used in the outpatient setting covered under Medicare Part B, which is two or more patients performing either the same or different activity, as opposed to the IRF definition of two to six patients performing the same or similar activities. However, given the greater degree of similarity between the IRF and SNF settings in terms of the intensity of therapy and patient acuity, we believe that the IRF PPS definition would be more appropriate in the SNF setting.

Accordingly, for the reasons discussed previously, we are proposing to define group therapy in the SNF Part A setting as a qualified rehabilitation therapist or therapy assistant treating two to six patients at the same time who are performing the same or similar activities. We believe this definition would offer therapists more clinical flexibility when determining the appropriate number for a group, without compromising the therapist's ability to manage the group and the patient's ability to interact effectively and benefit from group therapy.

We continue to believe that individual therapy is the preferred mode of therapy provision and offers the most tailored service for patients. As we stated in the FY 2012 proposed rule (76 FR 26387), while group therapy can play an important role in SNF patient care, group therapy is not appropriate for either all patients or for all conditions, and is primarily effective as a supplement to individual therapy, which we maintain should be considered the primary therapy mode and standard of care in therapy services provided to SNF residents.

Additionally, we continue to maintain that when group therapy is used in a SNF, therapists must document its use in order to demonstrate why it is the most appropriate mode of therapy for the patient who is receiving it. As stated in the FY 2012 proposed rule (76 FR 26388) regarding group therapy documentation, because group therapy is not appropriate for either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

B. Updating ICD–10 Code Mappings and Lists

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of PDPM, effective October 1, 2019. The PDPM utilizes ICD–10 codes in several ways, including to assign patients to clinical categories used for categorization in the PT, OT, and SLP components, as well as identifying certain comorbidities relevant for classification under the SLP and NTA components. The ICD–10 mappings and lists that would be used under PDPM, once implemented, are available on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*.

Each year, the ICD–10 Coordination and Maintenance Committee, a federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1, but has not yet done so.

As providers are required to follow the most up to date coding guidance issued by this committee in accordance with 45 CFR part 162, subpart J, it is essential that we be able to update our code mappings and lists consistent with the latest coding guidance. Therefore, to ensure that the ICD–10 mappings and lists used under PDPM reflect the most up to date codes possible, we propose to update any ICD–10 code mappings and lists used under PDPM, as well as the SNF GROUPER software and other such products related to patient classification and billing, through a subregulatory process which would consist of posting updated code mappings and lists on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*. More specifically, beginning with the updates for FY 2020 (see discussion below), nonsubstantive changes to the ICD–10 codes included on the code mappings and lists under the PDPM would be applied through the subregulatory process described above, and substantive revisions to the ICD–10 codes on the code mappings and lists used under the PDPM would be proposed and finalized through notice and comment rulemaking.

Nonsubstantive changes would be limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set, which Medicare providers are generally required to use. Our intent in applying these nonsubstantive changes through the proposed subregulatory process would be to keep the same conditions in the PDPM clinical categories and comorbidities lists, but ensure that the codes used to identify those conditions are synchronized with the most current ICD–10 medical code data set. For example, to the extent that the ICD–10–CM Coordination and Maintenance Committee changes an ICD–10 code for a comorbid condition on our comorbidities lists into one or more codes that provide additional detail, we would update the SNF GROUPER software and ICD–10 mappings and lists on the CMS website to reflect the new codes through the subregulatory process proposed above. By contrast, we would use notice and comment rulemaking to make substantive changes to the ICD–10 code mappings and lists under the PDPM. For the purposes of this policy, a substantive change would be defined simply as any change that does not fall within the definition of a nonsubstantive change—that is, changes that go beyond the intention of maintaining consistency with the most current ICD–10 medical code data set. For instance, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy would be substantive changes. Taking the example above, there may be situations in which the addition of one or more of these new codes to the list of comorbidities may not be appropriate. For example, the ICD–10 code for a particular condition is divided into two more detailed codes, one of which represents a condition that generally is predictive of the costs of care in a SNF and one of which is not. We would propose through notice and comment rulemaking to delete the code that does not reflect increased costs of care in a SNF from the list of comorbidities in the SNF GROUPER software because removing the code would constitute a substantive change. We propose to indicate all changes to codes in the GROUPER software by posting a complete ICD–10 mapping table, including new, discontinued, and modified codes, on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*. We also propose to report the complete list of ICD–10 codes associated with the SNF PDPM clinical categories and SLP/NTA comorbidities in the SNF GROUPER documentation, which is also posted on the PDPM website. All changes would be included in these documents, with substantive changes being included only after being finalized through notice and comment rulemaking.

We believe that the proposed subregulatory update process (by which nonsubstantive changes to the ICD–10 code mappings and lists used under PDPM as well as the SNF GROUPER software and other such products related to patient classification and billing would be posted on the CMS websites specified above), is the best way for us to convey information about changes to the ICD–10 medical code

data set that affect the code mappings and lists used under the PDPM. We believe the proposed subregulatory process would help ensure providers have the most up-to-date information as soon as possible, in the clearest and most useful format, as opposed to publishing each nonsubstantive change to the ICD–10 codes in a rule after notice and comment rulemaking.

Additionally, the proposed subregulatory process is in alignment with similar policies in the SNF PPS and the IRF PPS settings. For example, the SNF PPS already uses a subregulatory process to make nonsubstantive updates to the list of Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the consolidated billing (CB) provision of the SNF PPS. We post routine annual updates to the lists of codes that are included or excluded from CB on the SNF CB website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html*. The new codes identified in each update describe the same services that are subject to SNF PPS CB. No additional services are added by these routine updates; that is, these updates are necessary because of changes to the coding system, not because the services subject to SNF CB are being redefined. We believe the proposed subregulatory process to update ICD–10 codes associated with PDPM clinical categories and comorbidity lists is appropriate given that it is consistent with this subregulatory process already in use under the SNF PPS to make nonsubstantive coding updates.

Likewise, the IRF PPS also utilizes processes similar to that proposed here. In the FY 2007 IRF PPS final rule (71 FR 48360 through 48361), we implemented a similar subregulatory updating process for the IRF tier comorbidities list, and the FY 2018 IRF PPS final rule (82 FR 36267 through 36269) established a similar process for updating the ICD–10 code lists used for the IRF presumptive compliance methodology. Both the IRF tier comorbidities list and the IRF presumptive compliance methodology also use ICD–10 codes. Therefore, we believe the subregulatory process proposed in this rule is appropriate because it is also consistent with processes used in another Medicare setting.

We are proposing that this subregulatory process for updating the ICD–10 codes used under the PDPM would take effect beginning with the updates for FY 2020. The proposed ICD–10 code mappings and lists for use under the PDPM are available for download from the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*). These mappings and lists reflect the adoption of the ICD–10 Coordination and Maintenance Committee's draft changes to the ICD–10 medical code data sets, effective October 1, 2018. The version of these mappings and lists that is finalized in conjunction with the FY 2020 SNF PPS final rule would constitute the baseline for any future updates to the mappings and lists using the proposed process above.

C. Revisions to the Regulation Text

Along with our proposed revisions as discussed elsewhere in this proposed rule, we are also proposing to make certain revisions to the regulations text itself to reflect the revised assessment schedule under the PDPM, as finalized in the FY 2019 SNF PPS final rule (83 FR 39229). Specifically, we propose to revise the prescribed PPS assessment schedule as set forth in § 413.343(b), to reflect the elimination, upon the conversion from RUG–IV to PDPM on October 1, 2019, of all scheduled assessments after the initial 5-day, Medicare-required assessment. We note that even though this assessment is commonly referred to as the ''5-day'' assessment (reflecting its original 5-day assessment window), an additional 3 grace days have always been available beyond that window for its actual completion. Further, because those additional 3 grace days will be directly incorporated into the assessment window itself effective October 1, 2019 (as finalized in the FY 2019 SNF PPS final rule (83 FR 39231, 39232, and 39234)), thus resulting in an overall 8-day assessment window, we additionally propose to include a conforming revision in § 413.343(b) to make clear that the actual deadline for completing this assessment is no later than the 8th day of posthospital SNF care. In addition, because under the PDPM, there is only one scheduled patient assessment, we also propose to replace the phrase ''patient assessments'' in § 413.343(b) with the phrase ''an initial patient assessment.'' Accordingly, we propose to revise § 413.343(b) to state that the assessment schedule must include performance of an initial patient assessment no later than the 8th day of posthospital SNF care.

We further propose to revise the existing language in § 413.343(b) that additionally requires the completion of ''such other assessments that are necessary to account for changes in patient care needs,'' to state ''such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.'' As we finalized in the FY 2019 SNF PPS final rule (83 FR 39230 through 39234), the optional Interim Payment Assessment (IPA) will serve as the instrument for conducting assessments under the PDPM that the SNF determines are necessary after the completion of the 5-day, Medicare-required assessment to address clinical changes throughout a SNF stay. We believe that our proposed language is consistent with the expectation expressed in the FY 2019 SNF PPS final rule for SNFs ''. . . to provide excellent skilled nursing and rehabilitative care and continually monitor and document patient status'' (83 FR 39233), and makes clear that the SNF's responsibility in this context would include recognizing those situations that warrant a decision to complete an IPA in order to account appropriately for a change in patient status. Finally, to ensure consistency, we also propose to make a conforming revision to the regulations text in the introductory paragraph of § 409.30, so that it would use the same terminology of ''initial patient assessment'' as would appear in revised § 413.343(b). Specifically, in the introductory paragraph of § 409.30, we would replace the phrase ''the 5-day assessment'' with ''the initial patient assessment.'' We note that the regulations text in the introductory paragraph of § 409.30 would continue to specify that the assessment reference date (ARD) for this assessment must occur no later than the 8th day of posthospital SNF care, consistent with the instructions set forth in sections 2.8 and 2.9 of the RAI Version 3.0 Manual.

VI. Other Issues

A. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

1. Background

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Under the SNF QRP, the Secretary must reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i) of the Act for that fiscal year. For more information on the

requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566), and FY 2019 SNF PPS final rule (83 FR 39162 through 39272).

2. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we historically used for the selection of SNF QRP quality, resource use, and other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

3. Quality Measures Currently Adopted for the FY 2021 SNF QRP

The SNF QRP currently has 11 measures for the FY 2021 SNF QRP, which are set out in Table 12.

TABLE 12—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2021 SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan.	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

4. SNF QRP Quality Measure Proposals Beginning With the FY 2022 SNF QRP

In this proposed rule, we are proposing to adopt two process measures for the SNF QRP that, as required by section 1888(e)(6)(B)(i)(II) of the Act, would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain titled ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions from a post-acute care (PAC) provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.'' Given the length of this domain title, hereafter, we will refer to this quality measure domain as ''Transfer of Health Information.''

The two measures we are proposing to adopt are: (1) Transfer of Health Information to the Provider–Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient–Post-Acute Care (PAC). Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

In addition to the two measure proposals, we are proposing to update the specifications for the Discharge to Community—PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure.

We are seeking public comment on each of these proposals.

a. Proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current PAC setting.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and nine percent who were discharged to SNFs.[1] The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS). Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to a home health agency (HHA), 3 percent were discharged to an IRF, and 1 percent were discharged to an LTCH.[2] Of the Medicare FFS beneficiaries with a SNF stay in FY 2017, an estimated 21 percent were discharged or transferred to an acute care hospital, 11 percent discharged home with home health

[1] Tian, W. ''An all-payer view of hospital discharge to post-acute care,'' May 2016. Available at *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[2] Ibid.

services, and two percent discharged or transferred to another PAC setting (for example, an IRF, a hospice, or another SNF).[3]

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange network using an electronic health/medical record, and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[4] [5] [6] [7] [8] [9] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[10] [11] [12] [13] [14] [15] [16] [17] [18] [19]

Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission [20] defines as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.[21] When care transitions are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[22] [23] [24] [25] [26]

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.[27] [28] The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between $25 billion and $45 billion in wasteful spending in 2011.[29] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[30] [31]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[32] [33] [34] Individuals in PAC

[3] RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

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[20] The Joint Commission, ''Sentinel Event Policy'' available at *https://www.jointcommission.org/sentinel_event_policy_and_procedures/.*

[21] The Joint Commission. ''Sentinel Event Data Root Causes by Event Type 2004–2015.'' 2016. Available at *https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf.*

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settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[35] [36] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[37] A 2014 Office of Inspector General report found that almost one-tenth of Medicare beneficiaries experienced an ADE, such as delirium, bleeding, fall or injury, or constipation, during their stay in a SNF in 2011. Of these, two-thirds were classified as preventable.[38] Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[39] [40]

Patients in PAC settings are often taking multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Furthermore, inter-facility communication barriers delay resolving medication discrepancies during transitions of care.[41] Medication discrepancies are common,[42] and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.[43] [44] [45] Up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.[46] [47]

Transfer of a medication list between providers is necessary for medication reconciliation interventions, which have been shown to be a cost-effective way to avoid ADEs by reducing errors,[48] [49] [50] especially when medications are reviewed by a pharmacist using electronic medical records.[51]

(2) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[52] January 27, 2017, and August 3, 2017 [53] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure's reliability, components of face validity, and feasibility of being implemented across PAC settings. Overall, the TEP was supportive of the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4-June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

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[53] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT Medication–Profile-Transferred–Public-Comment-Summary-Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

(3) Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 Measures Under Consideration (MUC) list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange, and recommended that the medication information transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC–LTC.aspx*.

As part of the measure development and selection process, we also identified one NQF-endorsed quality measure similar to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014, and was also adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter.

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure addresses the transfer of information whereas the NQF-endorsed measure #0419 assesses the documentation of medications, but not the transfer of such information. This is important as the proposed measure assesses for the transfer of medication information for the proposed measure calculation. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419 does not.

After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments. Section 1899B(e)(2)(A) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF). However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For the reasons discussed above, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(5) Quality Measure Calculation

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) quality measure is calculated as the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at the time of discharge. The proposed measure denominator is the total number of SNF resident stays, ending in discharge to a ''subsequent provider,'' which is defined as a short-term general acute-care hospital, a skilled nursing facility (SNF), intermediate care (intellectual and developmental disabilities providers), home under care of an organized home health service organization or hospice, hospice in an institutional facility, an inpatient rehabilitation facility (IRF), an LTCH, a Medicaid nursing facility, an inpatient psychiatric facility, or a critical access hospital (CAH). These health care providers were selected for inclusion in the denominator because they are identified as subsequent providers on the discharge destination item that is currently included on the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at the time of discharge. For additional technical information about this proposed

measure, we refer readers to the document titled, ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. The data source for the proposed quality measure is the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section VI.A.8.c. of this proposed rule.

b. Proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure

Beginning with the FY 2022 SNF QRP, we are proposing to adopt the Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure, a measure that satisfies the IMPACT Act domain of Transfer of Health Information, with data collection for discharges beginning October 1, 2020. This process-based measure assesses whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice.

(1) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.[54] Of the Medicare FFS beneficiaries with a SNF stay in fiscal year 2017, an estimated 11 percent were discharged home with home health services, 41 percent were discharged home with self-care, and 0.2 percent were discharged with home hospice services.[55]

The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a patient safety risk, often life-threatening.[56] [57] [58] [59] [60] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[61] [62] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[63] [64] [65] The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse effects. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[66] [67]

Finally, the transfer of a patient's discharge medication information to the patient, family, or caregiver is common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[68] [69] Most PAC EHR systems generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.[70]

(2) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS MMS Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[71] January 27, 2017,

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[63] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' *Journal of the American Geriatrics Society,* 2016, Vol. 64(11), pp. e166–e170.

[64] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R., ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' *JAMA,* 2011, Vol. 306(8), pp. 840–847.

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[71] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient

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and August 3, 2017 [72] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT- Medication Profile Transferred Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(3) Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated an 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(4) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 MUC list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.*

Section 1899B(e)(2)(A) of the Act, requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF-endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF-endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient-Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(5) Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to the Patient-Post-Acute Care (PAC) measure would be based on the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge.

The proposed measure denominator is the total number of SNF resident stays ending in discharge to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization, or a hospice. These locations were selected for inclusion in the denominator because they are identified as home locations on the discharge destination item that is currently included on the MDS. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge. For technical information about this proposed measure we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Data for the proposed quality measure would be calculated using data from the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we are

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Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

[72] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

proposing for this measure, we refer readers to section VI.A.8.c. of this proposed rule.

c. Proposed Update to the Discharge to Community—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the Discharge to Community—PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure. This measure reports a SNF's risk-standardized rate of Medicare FFS residents who are discharged to the community following a SNF stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. We adopted this measure in the FY 2017 SNF PPS final rule (81 FR 52021 through 52029).

In the FY 2017 SNF PPS final rule (81 FR 52025), we addressed public comments recommending exclusion of SNF residents who were baseline NF residents, as these residents lived in a NF prior to their SNF stay and may not be expected to return to the community following their SNF stay. In the FY 2018 SNF PPS final rule (82 FR 36596), we addressed public comments expressing support for a potential future modification of the measure that would exclude baseline NF residents; commenters stated that the exclusion would result in the measure more accurately portraying quality of care provided by SNFs, while controlling for factors outside of SNF control.

We assessed the impact of excluding baseline NF residents from the measure using CY 2015 and CY 2016 data, and found that this exclusion impacted both patient- and facility-level discharge to community rates. We defined baseline NF residents as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and qualifying hospitalization for measure inclusion. Baseline NF residents represented 10.4 percent of the measure population after all measure exclusions were applied. Observed resident-level discharge to community rates were significantly lower for baseline NF residents (2.37 percent) compared with non-NF residents (53.32 percent). The national observed resident-level discharge to community rate was 48.01 percent when baseline NF residents were included in the measure, increasing to 53.32 percent when they were excluded from the measure. After excluding baseline NF residents, 38.5 percent of SNFs had an increase in their risk-standardized discharge to community rate that exceeded the increase in the national observed resident-level discharge to community rate.

Based on public comments received and our impact analysis, we are proposing to exclude baseline NF residents from the Discharge to Community—PAC SNF QRP measure beginning with the FY 2020 SNF QRP, with baseline NF residents defined as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and hospitalization.

For additional technical information regarding the Discharge to Community—PAC SNF QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We are inviting public comment on this proposal.

5. SNF QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and concepts under consideration listed in the Table 13 for future years in the SNF QRP.

TABLE 13—FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADES) UNDER CONSIDERATION FOR THE SNF QRP

Assessment-Based Quality Measures and Measure Concepts:
Functional maintenance outcomes.
Opioid use and frequency.
Exchange of electronic health information and interoperability.
Claims-Based:
Healthcare-Associated Infections in Skilled Nursing Facility (SNF)—claims-based.
Standardized Patient Assessment Data Elements (SPADEs):
Cognitive complexity, such as executive function and memory.
Dementia.
Bladder and bowel continence including appliance use and episodes of incontinence.
Care preferences, advance care directives, and goals of care.
Caregiver Status.
Veteran Status.
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation.

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2020 SNF PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts

6. Proposed Standardized Patient Assessment Data Reporting Beginning With the FY 2022 SNF QRP

Section 1888(e)(6)(B)(i)(III) of the Act requires that, for fiscal years 2019 and each subsequent year, SNFs must report standardized patient [73] assessment data (SPADE) required under section

[73] In the FY 2018 SNF PPS final rule, we used the term ''standardized resident assessment data'' to refer to standardized assessment data elements collected from SNF residents. However, in this proposed rule and going forward, we will use the term ''standardized patient assessment data'' to refer to the collect of SPADEs from SNF residents.

1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit SPADEs under applicable reporting provisions (which, for SNFs, is the SNF QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

In the FY 2018 SNF PPS proposed rule (82 FR 21059 through 21076), we proposed to adopt SPADEs that would satisfy the first five categories. In the FY 2018 SNF PPS final rule, commenters expressed support for our adoption of SPADEs in general, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs. However, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 36598 through 36600). In addition, we noted our intention to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid, and appropriate for their intended use (82 FR 36599).

We did, however, finalize the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported by SNFs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (2) Medical conditions and comorbidities: The data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by SNFs for the calculation of quality measures.

Since we issued the FY 2018 SNF PPS final rule, SNFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the SPADEs, as described more fully below, and believe that this testing supports the use of the SPADEs in our PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that SNFs would be required to report these SPADEs beginning with the FY 2022 SNF QRP. If finalized as proposed, SNFs would be required to report these data with respect to SNF admissions and discharges that occur between October 1, 2020 and December 31, 2020 for the FY 2022 SNF QRP. Beginning with the FY 2023 SNF QRP, we propose that SNFs must report data with respect to admissions and discharges that occur during the subsequent calendar year (for example, CY 2021 for the FY 2023 SNF QRP, CY 2022 for the FY 2024 SNF QRP).

We are also proposing that SNFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission only will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

In selecting the proposed SPADEs below, we considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADE. In selecting the proposed SPADEs below, we also took into consideration the following factors with respect to each data element:

(1) Overall clinical relevance;

(2) Interoperable exchange to facilitate care coordination during transitions in care;

(3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and

(4) Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed below, we additionally drew on input from several sources, including TEPs held by our data element contractor, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element contractor (hereafter ''National Beta Test'').

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test are available in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described above. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

7. Proposed Standardized Patient Assessment Data by Category

a. Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in

PAC patient and resident populations.[74] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[75] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[76] [77] [78] and promising treatments for severe traumatic brain injury are currently being tested.[79] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[80] [81] [82] [83] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[84]

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized patient assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable standardized patient assessment data elements assessing cognitive function and mental status are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

The data elements related to cognitive function and mental status were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21063). In response to our proposals, a few commenters noted that the proposed data elements did not capture some dimensions of cognitive function and mental status, such as functional cognition, communication, attention, concentration, and agitation. One commenter also suggested that other cognitive assessments should be considered for standardization. Another commenter stated support for the standardized assessment of cognitive function and mental status, because it could support appropriate use of skilled therapy for beneficiaries with degenerative conditions, such as dementia, and appropriate use of medications for behavioral and psychological symptoms of dementia.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

- Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21061), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[85] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[86]

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: The MDS used by SNFs and the IRF–PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/*

[74] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[75] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[76] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–211.

[77] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[78] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[79] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[80] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[81] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[82] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[83] Wagenaar D., Colenda C.C., Kreft M., Sawade J., Gardiner J., Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[84] Crespy S.D., Van Haitsma K., Kleban M., Hann C.J. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

[85] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[86] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

IMPACT-Act-Downloads-and-Videos.html.

The data elements that comprise the BIMS were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21061). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the BIMS as standardized patient assessment data elements. Other commenters were critical of the BIMS, noting its limitations for assessing mild cognitive impairment and functional cognition. Another stated that the BIMS should be administered with respect to discharge, as well as admission to capture changes during the stay. One expressed concern that the BIMS cannot be completed by patients and residents who are unable to communicate.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements and the TEP supported the assessment of patient or resident cognitive status at both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters also expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment (MCI). A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient's condition and will take this feedback into consideration in the development of future standardized assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we are proposing that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the BIMS as standardized patient assessment data for use in the SNF QRP.

- Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21061), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[87] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: A four-item version of the CAM is used in the MDS in SNFs and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We are proposing the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The data elements that comprise the CAM were first proposed as standardized patient assessment data

[87] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' *J of Hospital Med* 8(9): 500–505.

elements in the FY 2018 SNF PPS proposed rule (82 FR 21061). In that proposed rule, we stated that the proposal was informed by input we received on the CAM through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination and, therefore, contribute to quality improvement. We also stated that those commenters had noted the CAM is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the CAM as standardized patient assessment data elements, with one noting that it distinguishes delirium or reversible confusion from other types of cognitive impairments to share across settings for care coordination.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the CAM data elements, the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the CAM as standardized patient assessment data elements for use in the SNF QRP.

b. Patient Health Questionnaire—2 to 9 (PHQ–2 to 9)

We are proposing that the Patient Health Questionnaire—2 to 9 (PHQ–2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ–2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ–9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ–2 to 9, refers to an embedded a skip pattern that transitions residents with a threshold level of symptoms in the PHQ–2 to the longer assessment of the PHQ–9. The skip pattern is described further below.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ–2 to 9 is based on the PHQ–9 mood interview. The PHQ–2 consists of questions about only the first two symptoms addressed in the PHQ–9: Depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ–2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.[88] [89] If a patient demonstrates signs of depressed mood and anhedonia under the PHQ–2, then the patient is administered the lengthier PHQ–9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview assessment for residents who fail to report the cardinal symptoms of depression. The design of the PHQ–2 to 9 reduces the burden that would be associated with the full PHQ–9, while ensuring that patients with indications of depressive symptoms based on the PHQ–2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ–2) and the MDS for SNFs (PHQ–9). We are proposing altering the administration instructions for the existing data elements to adopt the PHQ–2 to 9 gateway logic, meaning that administration of the full PHQ–9 is contingent on resident responses to questions about the cardinal symptoms of depression. For more information on the PHQ–2 to 9, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-*

[88] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). ''Validity of the Patient Health Questionnaire 2 (PHQ–2) in identifying major depression in older people.'' *J of the A Geriatrics Society,* 55(4): 596–602.

[89] Löwe, B., Kroenke, K., & Gräfe, K. (2005). ''Detecting and monitoring depression with a two-item questionnaire (PHQ–2).'' *J of Psychosomatic Research,* 58(2): 163–171.

Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

The PHQ–2 data elements were first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063). In that proposed rule we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ–2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* That proposed rule was also informed by public input through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions of the PHQ depression screener: The PHQ–2; the PHQ–9; and the PHQ–2 to 9 with the skip pattern design. Many commenters provided feedback on using the PHQ–2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC provider types was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ–9, which exhibits higher specificity,[90] for patients and residents who showed signs and symptoms of depression on the PHQ–2. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal to use the PHQ–2 in the FY 2018 SNF PPS proposed rule, a few commenters supported screening residents for depression with the PHQ–2. One commenter opposed the replacement of the PHQ–9 on the MDS with PHQ–2 because of the clinical significance of depression on quality of care and resident outcomes in the SNF population. Another expressed concern about the use of multi-step ''gateway'' questions, because use of the PHQ–2 and PHQ–9 may result in data not being standardized across settings and providers gathering data unrelated to the appropriateness of care.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the PHQ–2 to 9 was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the PHQ–2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the PHQ–2 to 9. The TEP was supportive of the PHQ–2 to 9 data element set as a screener for signs and symptoms of depression. The TEP's discussion noted that symptoms evaluated by the full PHQ–9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ–2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ–2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for depression, stakeholder input, and strong test results, we are proposing that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the PHQ–2 to 9 data elements as standardized patient assessment data elements for use in the SNF QRP.

c. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and

[90] Arroll B., Goodyear-Smith F., Crengle S., Gunn J., Kerse N., Fishman T., et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–353. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

A TEP convened by our data element contractor provided input on all of the proposed data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, this TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21073) public comment period. A comment across all special services, treatments, and interventions data elements requested that the additional reporting burden of the special services, treatments, and interventions data elements be addressed in payment calculations. Another comment submitted for several special services, treatments, and interventions data elements requested additional time be allowed before the providers are required to submit these data. One commenter expressed concern about increased reporting burden of the data elements proposed in FY 2018 because they would require an additional look-back time frame. Several commenters supported the inclusion of nutritional data elements as standardized data elements noting their importance in capturing information on care coordination and safe care transitions. One commenter noted the limitations of the nutritional data elements, namely that they do not capture information on swallowing or the clinical rationale for feeding/nutrition needs.

Information on data element performance in the National Beta Test, which collected data between November 2017 and August 2018, is reported within each data element proposal below. Clinical staff who participated in the National Beta Test supported these data elements because of their importance in conveying patient or resident significant health care needs, complexity, and progress. However, clinical staff also noted that, despite the simple ''check box'' format of these data element, they sometimes needed to consult multiple information sources to determine a patient's or resident's treatments.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

(1) Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, and can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally, or more commonly, given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

The Chemotherapy (IV, Oral, Other) data element consists of a principal data element (Chemotherapy) and three response option sub-elements: IV chemotherapy, which is generally resource-intensive; Oral chemotherapy, which is less invasive and generally requires less intensive administration protocols; and a third category, Other, provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to chemotherapy delivery by other routes (for example, intraventricular or intrathecal). If the assessor indicates that the resident is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (for example, IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. We are proposing to expand the existing Chemotherapy data element in the MDS to include sub-elements for IV, Oral, and Other. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-*

Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

The Chemotherapy data element was first proposed as a standardized patient assessment data element in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. We also stated that those commenters had noted that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Chemotherapy (IV, Oral, Other) as standardized patient assessment data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for chemotherapy, stakeholder input, and strong test results, we are proposing, we are proposing that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the SNF QRP.

(2) Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The Radiation data element is currently in use in the MDS in SNFs. For more information on the Radiation data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Radiation data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed support for the Radiation data element, noting its importance and clinical usefulness for patients and residents in PAC settings, due to the side effects and consequences of radiation treatment on patients and residents that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary

report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Radiation as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the SNF QRP.

(3) Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

We are proposing that the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065), oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here captures patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three response option sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as >=14 hours per day); Intermittent; or High-concentration oxygen delivery system. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the resident is receiving oxygen therapy on the principal oxygen therapy data element, the assessor then would indicate the type of oxygen the patient receives (for example, Continuous, Intermittent, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS in SNFs (''Oxygen Therapy''), previously used in the OASIS (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 >40 percent''). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Oxygen Therapy (Continuous, Intermittent) data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to

facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the adoption of Oxygen Therapy (Continuous, Intermittent) as a standardized patient assessment data element. Another commenter recommended that an option for high-concentration oxygen be added. In response to public comments, we added a third sub-element for ''High-Concentration Oxygen Delivery System'' to the Oxygen Therapy data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing oxygen therapy, stakeholder input, and strong test results, we are proposing that the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element as standardized patient assessment data for use in the SNF QRP.

(4) Respiratory Treatment: Suctioning (Scheduled, as Needed)

We are proposing that the Suctioning (Scheduled, As needed) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients and residents with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of a principal data element, and two sub-elements: Scheduled; and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour; As needed means suctioning only when indicated. If the assessor indicates that the resident is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (for example, Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __hours]''). We are proposing to expand the existing Suctioning data element on the MDS to include sub-elements for Scheduled and As Needed. For more information on the Suctioning data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient

Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Suctioning data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066). In that proposed rule, we stated that the proposal was informed by input we received on the Suctioning data element currently included in the MDS in SNFs through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for this data element. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also stated that those commenters had suggested that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Suctioning (Scheduled, As needed) as a standardized patient assessment data element. One commenter objected to ''scheduled'' suctioning as a response option due to a clinical practice guideline recommendation that suctioning should only be performed when clinically indicated and not on a scheduled basis.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Suctioning data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the SNF QRP.

(5) Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS in SNFs (''Tracheostomy care''). For more information on the Tracheostomy Care data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality

Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Tracheostomy Care data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067). In that proposed rule, we stated that the proposal was informed by input we received on the Tracheostomy Care data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, supported this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, we received a few comments in support of the adoption of Tracheostomy Care as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the SNF QRP.

(6) Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BIPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two response option sub-elements: BiPAP and CPAP. If the assessor indicates that the resident is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (for example, BIPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS for the SNF setting (''Non-invasive Mechanical Ventilator (BiPAP/CPAP)''). We are proposing to expand the existing BiPAP/CPAP data element on the MDS, retaining and relabeling the BiPAP/CPAP data element to be Non-invasive Mechanical Ventilator (BiPAP, CPAP), and adding two sub-elements for BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BIPAP, CPAP) data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Non-invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21067). In that proposed rule, we stated that the proposal was informed by input we received through a call for input

published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on a single data element, BiPAP/CPAP, that captures equivalent clinical information but uses a different label than the data element currently used in the MDS in SNFs and LCDS in LTCHs, expressed support for this data element, noting the feasibility of these items in PAC, and the relevance of this data element for facilitating care coordination and supporting care transitions. In addition, we also stated that some commenters supported separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Non-Invasive Mechanical Ventilator (BiPAP, CPAP) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the SNF QRP.

(7) Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia, and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[91]

The proposed data element, Invasive Mechanical Ventilator, consists of a single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. The MDS currently assesses invasive mechanical ventilation with the Ventilator or Respirator data element. We are proposing to rename this data element in the MDS to be Invasive Mechanical Ventilator. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning''). Input submitted from August 12 to September 12, 2016 expressed support for this data

[91] Wunsch, H., Linde-Zwirble, W. T., Angus, D. C., Hartman, M. E., Milbrandt, E. B., & Kahn, J. M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' *Critical Care Med* 38(10): 1947–1953.

element, highlighting the importance of this information in supporting care coordination and care transitions. We also stated that some commenters had expressed concern about the appropriateness for standardization given: The prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' we received is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the adoption of Invasive Mechanical Ventilator as a standardized patient assessment data element. One commenter stated that a data element to indicate ''weaning'' is important because it indicates higher resource utilization.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the SNF QRP.

(8) Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069), when we proposed a similar data element related to IV medications, IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter. IV medications are administered via intravenous push, single, intermittent, or continuous infusion through a catheter placed into the vein. Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medications data element (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when the bioavailability of the oral form of the medication would be inadequate to kill the pathogen or an oral form of the medication does not exist. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the FY 2018 SNF PPS proposed rule. We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Medications element with the data currently collected in the LCDS.

If the assessor indicates that the resident is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (for

example, Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. We are proposing to expand the existing IV Medications data element in the MDS to include sub-elements for Antibiotics, Anticoagulants, Vasoactive Medications, and Other. For more information on the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

An IV Medications data element was first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069). In that proposed rule, we stated that the proposal was informed by input we received on Vasoactive Medications through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element with one noting the importance of this data element in supporting care transitions. We also stated that those commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the SNF QRP.

(9) Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21069), transfusion refers to introducing blood or blood products into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element consists of the single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs (''Transfusions'') and a data element tested in the PAC PRD (''Blood Transfusions'') was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Transfusions as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for transfusions, stakeholder input, and strong test results, we are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Transfusions data element as standardized patient assessment data for use in the SNF QRP.

(10) Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility for treatment. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis and Peritoneal dialysis. If the assessor indicates that the resident is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis or Peritoneal dialysis). Dialysis data elements are currently included on the MDS in SNFs and the LCDS in LTCHs and assess the overall use of dialysis. We are proposing to expand the existing Dialysis data element in the MDS to include sub-elements for Hemodialysis and Peritoneal dialysis.

As the result of public feedback described below, in this proposed rule, we are proposing a data element that includes the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal dialysis). For more information on the Dialysis data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Dialysis data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070). In that proposed rule, we stated that the proposal was informed by input we received on a singular Hemodialysis data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. We are proposing the version of the Dialysis element that

includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of Dialysis (Hemodialysis, Peritoneal dialysis) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the Dialysis data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data for use in the SNF QRP.

(11) Intravenous (IV) Access (Peripheral IV, Midline, Central line)

We are proposing that the IV Access (Peripheral IV, Midline, Central line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071), patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed data element, IV Access (Peripheral IV, Midline, Central line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments. For more information on the IV Access (Peripheral IV, Midline, Central line) data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The IV Access data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071). In that proposed rule, we stated that the proposal was informed by input we received on one of the PAC PRD data elements, Central Line Management, a type of IV access, through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters noted feasibility and importance of facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with expert input, described below, we created an overarching IV Access data element with sub-elements for other types of IV access in addition to central lines (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the IV Access (Peripheral IV, Midline,

Central line, Other) as a standardized patient assessment data element, with one commenter encouraging clear guidance in the Resident Assessment Instrument User Manual to distinguish between coding instructions for this data element and those for other data elements on IV treatments.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Access data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data for use in the SNF QRP.

(12) Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and the maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as air embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS in SNFs, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and OASIS. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Parenteral/IV Feeding data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072). In that proposed rule, we stated that the proposal was informed by input we received on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD) through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Parenteral/IV Feeding as a standardized patient assessment data element, with one requesting ''universal'' guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-*

Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for parenteral/IV feeding, stakeholder input, and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the SNF QRP.

(13) Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and, therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[92] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF–PAI for IRFs (''Tube/Parenteral Feeding''), assesses use of both feeding tubes and parenteral nutrition. For more information on the Feeding Tube data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Feeding Tube data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21072). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on an Enteral Nutrition data element (the Enteral Nutrition data item is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Feeding Tube as a standardized patient assessment data element. Another commenter recommended that the term ''enteral feeding'' be used instead of ''feeding tube.''

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-*

[92] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Feeding Tube data element as standardized patient assessment data for use in the SNF QRP.

(14) Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[93]

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients and residents on mechanically altered diets also require additional nursing supports, such as individual feeding or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element is currently included on the MDS for SNFs. A related data element (''Modified food consistency/supervision'') is currently included on the IRF–PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' For more information on the Mechanically Altered Diet data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Mechanically Altered Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073).

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported the adoption of the Mechanically Altered Diet as a standardized patient assessment data element, with one requesting ''universal'' guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Mechanically Altered Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

[93] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the SNF QRP.

(15) Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21073), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient's or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients and residents in PAC provides insight on the clinical complexity of these patients and residents and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. This data element is currently in use in the MDS in SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Therapeutic Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21073). In response to our proposal in the FY 2018 SNF PPS proposed rule, commenters supported the adoption of the Therapeutic Diet as a standardized patient assessment data element. Two commenters stated that the coding instructions should be clear and more broadly applicable to patients and residents in all PAC settings. Another two commenters suggested that the definition of Therapeutic Diet should be aligned with the Academy of Nutrition and Dietetics' definition, with one stating that ''medically altered diet'' should be added to the nutritional data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Therapeutic Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic data element as standardized patient assessment data for use in the SNF QRP.

(16) High Risk Drug Classes: Use and Indication

We are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the

U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[94] Moreover, changes in a patient's condition, medications, and transitions between care settings put patients and residents at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[95]

ADEs are known to occur across different types of healthcare settings. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[96] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[97] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[98] In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge from a hospital.[99] [100] [101] ADEs are more common among older adults, who make up most patients receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.[102]

Understanding the types of medication a patient is taking and the reason for its use are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.[103] We are proposing one High-Risk Drug Class data element with six sub-elements. The six medication classes response options are: anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular: bleeding risk is associated with anticoagulants and antiplatelets; [104] [105] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics; [106] misuse is associated with opioids; [107] fractures and strokes are associated with antipsychotics; [108] [109] and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,[110] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[111] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.[112]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a resident is taking any medications within the six drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the resident is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the resident is taking anticoagulant medication, the assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. Similar data elements on some high-risk medications are already included in the MDS. We are proposing to modify and expand existing data elements in the MDS to include additional high-risk drug classes and indications for all drug classes. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

[94] U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI–06–09–00090. November 2010.

[95] Boockvar K.S., Liu S., Goldstein N., Nebeker J., Siu A., Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. Qual Saf Health Care. 2009;18(1):32–6.

[96] Gandhi T.K., Seger A.C., Overhage J.M., et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6.doi:10.1097/PTS.0b013e3181dcae06.

[97] Gurwitz J.H., Field T.S., Judge J., Rochon P., Harrold L.R., Cadoret C., et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med.* 2005; 118(3):251±8. Epub 2005/03/05. *https://doi.org/10.1016/j.amjmed.2004.09.018* PMID: 15745723.

[98] Hug B.L., Witkowski D.J., Sox C.M., Keohane C.A., Seger D.L., Yoon C., Matheny M.E., Bates D.W.. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. Kidney Int. 2009; 76:1192–1198. [PubMed: 19759525].

[99] Barnsteiner J.H. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31–36.

[100] Rozich J., Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[101] Gleason K.M., Groszek J.M., Sullivan C., Rooney D., Barnard C., Noskin G.A. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm.* 2004;61(16):1689–1695.

[102] Shehab N., Lovegrove M.C., Geller A.I., Rose K.O., Weidle N.J., Budnitz D.S. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

[103] Ibid.

[104] Shoeb M., Fang M.C. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239–013–0899–7.

[105] Melkonian M., Jarzebowski W., Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

[106] Hamnvik O.P., McMahon G.T. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[107] Naples J.G., Gellad W.F., Hanlon J.T. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32 (4):725–735.

[108] Rigler S.K., Shireman T.I., Cook-Wiens G.J., Ellerbeck E.F., Whittle J.C., Mehr D.R., Mahnken J.D. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366].

[109] Wang S., Linkletter C., Dore D. et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

[110] Faulkner C.M., Cox H.L., Williamson J.C. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[111] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2019; 00:1–21. DOI: 10.1111/jgs.15767.

[112] Li Y., Salmasian H., Harpaz R., Chase H., Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011: 768–76.

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data element contractor. At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications.[113] A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited public input on data elements related to medication reconciliation during a public input period from April 26 to June 26, 2017. Several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stated that the items seemed feasible and clinically useful. A few commenters were critical of the choice of 10 drug classes posted during that comment period, arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. The TEP acknowledged the challenges of assessing medication safety, but were supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes and using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete this SPADE would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing high-risk drugs and for whether or not indications are noted for high-risk drugs, stakeholder input, and strong test results, we are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the SNF QRP.

d. Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

Below we discuss our proposals for data elements related to the medical

[113] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.[114] We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.[115] [116] [117]

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. The SPADEs will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through: facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

We are inviting comment that apply specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities, specifically on:

(1) Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities)

In acknowledgement of the opioid crisis, we specifically are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent collection of the data below through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical condition and comorbidity data under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.[118] In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.[119] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[120] Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step towards appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.[121] Further, the focus on pain *interference,* as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in this proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the FY 2017 SNF PPS final rule (81 FR 52039) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) SNF QRP measure which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s), which includes issues associated with use and misuse of opioids for pain management, when such issues were identified.

[114] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[115] . Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[116] Fishman S.M., Carr D.B., Hogans B., et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[117] Fishman S.M., Young H.M., Lucas Arwood E., et al. Core competencies for pain management: results of an interprofessional consensus summit. Pain Med Malden Mass. 2013;14(7):971–981. doi:10.1111/pme.12107.

[118] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (US); 2011. *http://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[119] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[120] National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.* Washington DC: National Academies of Sciences, Engineering, and Medicine.; 2017.

[121] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

We also note that the proposed SPADE related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly,[122] [123] [124] an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[125] [126] [127]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term opioid use off of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[128] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis [129] which includes ''Better Pain Management.''

The Pain Interference data elements consist of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain effects a resident's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a resident's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a resident's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. We are proposing to expand and modify the existing Pain data elements in the MDS to include the Pain Effect on Sleep; Pain Interference with Therapy Activities; and Pain Interference with Day to Day Activities data elements. For more information on the Pain Interference data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We held a public input period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference—Therapy Activities; Pain Interference—Other Activities) in a second call for public input, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,''

[122] Chau, D.L., Walker, V., Pai, L., & Cho, L.M. (2008). Opiates and elderly: use and side effects. *Clinical interventions in aging, 3*(2), 273–8.

[123] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[124] Solomon, D.H., Rassen, J.A., Glynn, R.J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S.. (2010). *Archives Internal Medicine,* 170(22):1979–1986.

[125] Byrd L. Managing chronic pain in older adults: a long-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging.* 2013;21(12):34–40.

[126] Kligler, B., Bair, M.J., Banerjea, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine, 33*(Suppl 1): 16. *https://doi.org/10.1007/s11606-018-4323-z.*

[127] Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine, 166*(7):493–505.

[128] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. *https://paltc.org/opioids%20in%20nursing%20homes.*

[129] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the standardized patient assessment data elements. The TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the Pain data elements and was encouraged by the fact that this portion of the assessment goes beyond merely measuring the presence of pain. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for the effect of pain on function, stakeholder input, and strong test results, we are proposing that the three Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data for use in the SNF QRP.

e. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients and residents will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients and residents continue to have their vision and hearing needs met when they leave the facility.

In alignment with our Meaningful Measures Initiative, we expect accurate and individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will: Enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

Comments on the category of impairments were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21076) public comment period. A commenter stated hearing, vision, and communication assessments should be administered at the beginning of assessment process, to provide evidence about any sensory deficits that may affect the patient's or resident's ability to participate in the assessment and to allow the assessor to offer an assistive device. Another commenter supported the decision to assess hearing and vision with respect to admission only and not discharge, and to use existing MDS items for hearing and vision, thereby not creating additional burden.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments.

(1) Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, social functioning, and emotional health.[130] [131] Treatment and

[130] Dalton D.S., Cruickshanks K.J., Klein B.E., Klein R, Wiley T.L., Nondahl D.M. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[131] Hawkins K., Bottone F.G., Jr., Ozminkowski R.J., et al. The prevalence of hearing impairment

accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[132] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[133] [134] [135] higher rates of incident cognitive impairment and cognitive decline,[136] and less time in occupational therapy.[137] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Hearing data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075). In that proposed rule, we stated that the proposal was informed by input we received on the PAC PRD form of the data element (''Ability to Hear'') through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported Hearing as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions about use of a hearing device by the resident should be more clearly defined. Commenters were supportive of adopting the Hearing data element for standardized cross-setting use, noting that it would help address the needs of patient and residents with disabilities and that failing to identify impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can validate other information obtained from patient assessment.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the SNF QRP.

(2) Vision

We are proposing that the Vision data element meets the definition of SPADE with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076), evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and residents and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive

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and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[132] Horn K.L., McMahon N.B., McMahon D.C., Lewis J.S., Barker M., Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[133] Sprinzl G.M., Riechelmann H. Current trends in treating hearing loss in elderly people: A review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[134] Lin F.R., Thorpe R., Gordon-Salant S., Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[135] Hawkins K., Bottone F.G., Jr., Ozminkowski R.J., et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[136] Lin F.R., Metter E.J., O'Brien R.J., Resnick S.M., Zonderman A.B., Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[137] Cimarolli V.R., Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

symptoms.[138] [139] [140] [141] [142] [143] [144] Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the SNF setting for care planning and defining resource use.

The proposed data element consists of the single Vision data element (Ability To See in Adequate Light) that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS in SNFs and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS. For more information on the Vision data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Vision data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076). In that proposed rule, we stated that the proposal was informed by input we received on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. Although the data element in public comment differed from the proposed data element, input submitted from August 12 to September 12, 2016 supported assessing vision in PAC settings and the useful information a vision data element would provide. We also stated that commenters had noted that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element in SNFs over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, two commenters supported Vision as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions for use of a vision device by the resident should be more clearly defined. Commenters recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. One commenter supported having a SPADE for vision across PAC settings, but stated it captures only basic information for risk adjustment, and more detailed information would need to be collected to use it as an outcome measure.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to

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[138] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[139] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[140] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[141] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[142] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[143] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[144] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the SNF QRP.

f. Proposed New Category: Social Determinants of Health

(1) Proposed Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare based on those measures, after taking into account studies conducted by ASPE on social risk factors (described below) and other information, and based on an individual's health status and other factors. Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every three years, based on the factors referred to subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described above in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. In this rule, we are proposing to collect and access data about social determinants of health (SDOH) to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail below. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section VI.A.7.f.(2) of this proposed rule.

We are also proposing to use the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0, described as a PAC assessment instrument under section 1899B(a)(2)(B) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC health care providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in section VI.A.7.f.(2) of this proposed rule. Subparagraphs (A) and (B) of section 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed below, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering, and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature review. Based on the information collected, the 2016 NASEM panel report titled, ''Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors,'' concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These factors are discussed at length in chapter 2 of the NASEM report, titled ''Social Risk Factors.'' [145] Consequently NASEM framed the results of its report in terms of ''social risk factors'' rather than ''socioeconomic status'' or ''sociodemographic status.'' The full text of the ''Social Risk Factors'' NASEM report is available for reading on the website at *https://www.nap.edu/read/21858/chapter/1.*

Each of the data elements we are proposing to collect and access pursuant to our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[146]

ASPE issued its first Report to Congress, titled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' pursuant to section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.[147] Using NASEM's social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) Dual enrollment in Medicare and Medicaid as a marker for low income, (2) residence in a low-income area, (3) Black race, (4) Hispanic ethnicity, and; (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been collected, the

[145] National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors.* Chapter 2. Washington, DC: The National Academies Press.

[146] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[147] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports.*

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, CMS' ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information relating to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible. The three components of this strategy are to: (1) Measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed above, ASPE's study, considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section VI.A.7.f.(1) of this proposed rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal below (in section VI.A.7.f.(2) of this proposed rule and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed above, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section VI.A.7.f.(2)(a) of this proposed rule; (2) Ethnicity, as described in section VI.A.7.f.(2)(a) of this proposed rule; (3) Preferred Language, as described in section VI.A.7.f.(2)(b) of this proposed rule; (4) Interpreter Services as described in section VI.A.7.f.(2)(b) of this proposed rule; (5) Health Literacy, as described in section VI.A.7.f.(2)(c) of this proposed rule; (6) Transportation, as described in section VI.A.7.f.(2)(d) of this proposed rule; and (5) Social Isolation, as described in section VI.A.7.f.(2)(e) of this proposed rule. These data elements are discussed in more detail below in section VI.A.7.f.(2) of this proposed rule. We welcome comment on this proposal.

(2) Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. Below we are proposing to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined above under section 2(d)(2)(B) of the IMPACT Act, we are also proposing to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We are proposing to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for

PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we are proposing under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of residents and patients, and to inform our understanding of resident and patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional SDOH, we are proposing to assess some of the factors relevant for patients and residents receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients and residents with identified needs with transportation programs, certified interpreters, or social support programs.

As previously mentioned and described in more detail below we are proposing to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health category: Race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations and state agencies, and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled ''Listening Session on Social Determinants of Health Data Elements: Summary of Findings,'' includes a list of participating stakeholders and their affiliations, and is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(a) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[148] [149] [150] [151] [152] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[153] For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower rates of having a usual source of care and receiving immunizations such as the flu vaccine.[154] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[155] However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.[156]

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF–PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[157] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino, and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

We are proposing to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data

[148] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[149] Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). Annual Review of Public Health. 37:375–394.

[150] 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

[151] Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). Unequal treatment: confronting racial and ethnic disparities in health care. Washington, DC, National Academy Press.

[152] Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. *J of Aging and Health.* 30(9):1406–1426.

[153] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/research/findings/nhqrdr/index.html.*

[154] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[155] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse.*aspx?lvl=4&lvlid=19.

[156] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[157] ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)''. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available from: *https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf.*

standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we are proposing two separate data elements: One for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards, a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, ''What is your race?'' We are proposing to include fourteen response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, ''Are you Hispanic, Latino/a, or Spanish origin?'' We are proposing to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano/a; (3) Puerto Rican; (4) Cuban; and, (5) Another Hispanic, Latino, or Spanish Origin.

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF–PAI and, OASIS.[158] [159] [160] [161] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[162] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[163] By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the US population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we are proposing to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the MDS. We are also proposing that SNFs that submit the Race and Ethnicity data elements with respect to admission will be considered to have submitted with respect to discharge as well, because it is unlikely that the results of these assessment findings will change between the start and end of the SNF stay, making the information submitted with respect to a resident's admission the same with respect to a resident's discharge.

(b) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).[164] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[165] [166] [167] Communication with individuals with LEP is an important component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing

[158] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. J Public Health Manag Pract. 22 Suppl 1: S33–42.

[159] Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: do you have REGAL data? Qual Manag Health Care. 21(3):176–87.

[160] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[161] ''Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).'' **Federal Register** 82: 39 (March 1, 2017) p. 12242.

[162] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[163] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[164] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[165] Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. *J Hosp Med.* 2010 May-Jun;5(5):276–82. doi: 10.1002/jhm.658.

[166] Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. *J Gen Intern Med.* 2017 Jun;32(6):632–639. doi: 10.1007/s11606–017–3999–9.

[167] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

high quality care. Understanding the communication assistance needs of residents and patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of residents and patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.[168]

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-reviewed research. The current preferred language data element in LCDS and MDS asks, ''What is your preferred language?'' Because the preferred language data element is open-ended, the patient or resident is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, ''Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.'' In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, ''Do you want or need an interpreter to communicate with a doctor or health care staff?'' and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's or resident's preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing resident and patient needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

Research consistently recommends collecting information about an individual's preferred spoken language and evaluating those responses for purposes of determining language access needs in health care.[169] However, using ''preferred spoken language'' as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient or resident. Therefore we are proposing to retain the Preferred Language and Interpreter Services data elements currently in use on the MDS.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the MDS, and describe above, as SPADEs with respect to the Social Determinants of Health category.

(c) Health Literacy

The Department of Health and Human Services defines health literacy as ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' [170] Similar to language barriers, low health literacy can interfere with communication between the provider and resident or patient and the ability for residents and patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.[171]

[168] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[169] Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7—April 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.*

[170] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

[171] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk

Continued

Health literacy is prioritized by Healthy People 2020 as an SDOH.[172] Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM noted that health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.[173] Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and residents and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF–PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, ''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'' Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability, (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S–TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[174] [175] The S–TOFHLA is a more complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.[176] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[177] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of SNF residents to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients and residents understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided at an appropriate literacy level based on individualized assessment of health literacy.[178] Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice, we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.[179] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the SILS question, described above for the Health Literacy data element, as SPADE under the Social Determinants of Health Category. We are proposing to add the Health Literacy data element to the MDS.

(d) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[180] Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me

factors. Washington, DC: The National Academies Press.

[172] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[173] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.* Washington, DC: 2016.

[174] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[175] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[176] University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available at *https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html.*

[177] Nurss, J.R., Parker, R.M., Williams, M.V., & Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: *http://www.peppercornbooks.com/catalog/information.php?info_id=5.*

[178] Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

[179] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

[180] Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. *J Community Health.* 38(5): 976–993.

from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient or resident would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[181]

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.[182] This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[183] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for SNF residents and patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at *https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare.*

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Transportation data element described above as SPADE with respect to the Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the MDS.

(e) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote area.[184] [185] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[186] [187] [188] Post-acute care providers are well-suited to design and implement programs to increase social engagement of patients and residents, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation in SNFs and across PAC settings would facilitate the identification of residents and patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress and asks, ''How often do you feel lonely or isolated from those around you?'' The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[189] The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how social isolation and loneliness impact health outcomes in adults 50

[181] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.www.aha.org/transportation.*

[182] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.*

[183] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

[184] Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. J of Aging and Health. 18(3): 359–384.

[185] Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). Leading Age. Available at *https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1*

[186] Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. BMJ Open. 7(5): e013778.

[187] Ong, A.D., Uchino, B.N., and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. *Gerontology.* 62:443–449.

[188] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health.* 152:157–171.

[189] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

years and older. We believe that adding a Social Isolation data element would be an important component of better understanding resident and patient complexity and the care goals of residents and patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In an effort to standardize the submission of social isolation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the MDS.

We are soliciting comment on these proposals.

8. Proposed Form, Manner, and Timing of Data Submission Under the SNF QRP

a. Background

We refer readers to the regulatory text at § 413.360(b) for information regarding the current policies for reporting SNF QRP data.

b. Update to the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

SNFs are currently required to submit MDS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) that will enable real-time upgrades over the next few years, and we are proposing to designate that system as the data submission system for the SNF QRP once it becomes available, but no later than October 1, 2021.

We are proposing to revise our regulatory text at § 413.360(a) by replacing ''Certification and Survey Provider Enhanced Reports (CASPER)'' with ''CMS designated data submission''. We are proposing to revise our regulatory text at § 413.360(d)(1) by replacing the reference to the ''Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP)'' with ''CMS designated data submission'' and § 413.360(d)(4) by replacing the reference to ''QIES ASAP'' with ''CMS designated data submission system'' effective October 1, 2019. In addition we are proposing to notify the public of any future changes to the CMS designated system using subregulatory mechanisms, such as website postings, listserv messaging, and webinars.

We invite public comments on this proposal.

c. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 SNF QRP

As discussed in section VI.A.4. of this proposed rule, we are proposing to adopt the Transfer of Health Information to Provider–Post-Acute Care (PAC) and Transfer of Health Information to Patient–Post-Acute Care (PAC) quality measures beginning with the FY 2022 SNF QRP. We also are proposing that SNFs would report the data on those measures using the MDS. SNFs would be required to collect data on both measures for residents beginning with October 1, 2020 discharges.

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

We invite public comment on this proposal.

d. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements

As discussed in section VI.A.6. of this proposed rule, we are proposing to adopt SPADEs beginning with the FY 2022 SNF QRP. We are proposing that SNFs would report the data using the MDS. Similar to the proposed schedule for reporting the Transfer of Health Information to the Provider–Post-Acute Care (PAC) and Transfer of Health Information to the Patient–Post-Acute Care (PAC) quality measures, SNFs would be required to collect the SPADEs for residents beginning with October 1, 2020 admissions and discharges. SNFs that submit data with respect to admission for the Hearing, Vision, Race, and Ethnicity SPADEs would be considered to have submitted data with respect to discharges. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

e. Proposed Data Reporting on Residents for the SNF Quality Reporting Program Beginning With the FY 2022 SNF QRP

We have received public input suggesting that the quality measures used in the SNF QRP should be calculated using data collected from all residents receiving SNF services, regardless of the residents' payer. This input was provided to us via comments requested about quality measure development on the CMS Measures Management System Blueprint website,[190] the TEPs held by our measure development contractor,[191] as well as through comments we received from stakeholders via our SNF QRP mailbox, and feedback received from the NQF-convened Measure Applications Partnership (MAP) as part of their recommendations on Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement.[192] Further, in the FY 2018 SNF PPS proposed rule (82 FR 21077), we sought input on expanding the reporting of quality data to include all residents, regardless of payer, so as to ensure that the SNF QRP makes publicly available information regarding the quality of the services furnished to the SNF population as a whole, rather than just those residents who have Medicare.

In response to that request for public input, several commenters, including MedPAC, submitted comments stating that they would be supportive of an effort to collect data specified under the SNF QRP from all SNF residents regardless of their payer. Benefits highlighted by commenters included that such data would serve to better inform beneficiaries on the broader quality of the entire SNF, as well as more comprehensive quality improvement efforts across payers. MedPAC also highlighted that while the data collection activity incurs some

[190] Public Comment Summary Report Posting for Transfer of Health Information and Care Preferences. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-Cross-Setting-Transfer-of-Health-Information-Quality-Meas.pdf.*

[191] Technical Expert Panel Summary Report: Development and Maintenance of Quality Measures for Skilled Nursing Facility Quality Reporting Program. April 2018. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/TEP-Summary-Report_April-2018_Development-and-Maintenance-of-Quality-Measures-for-SNF-QRP.pdf.*

[192] MAP Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement. Feb 2012. *http://www.qualityforum.org/Publications/2012/02/MAP_Coordination_Strategy_for_Post-Acute_Care_and_Long-Term_Care_Performance_Measurement.aspx.*

cost, some providers currently assess all residents routinely. For a more detailed discussion we refer readers to the FY 2018 final rule (82 FR 36603 through 36604).

Further, we believe that the most accurate representation of the quality provided in SNFs to Medicare residents would be best conveyed using data collected via the MDS on all SNF residents, regardless of payer.

Accordingly, we are proposing that for purposes of meeting the requirements of the SNF QRP, SNF would be required to collect and submit MDS data on all SNF residents regardless of their payer. We believe that this proposal will ensure that Medicare residents are receiving the same quality of SNF care as other residents.

While we appreciate that collecting quality data on all residents regardless of payer may create additional burden, we are aware that many SNFs currently collect MDS data on all residents, regardless of their payer, and that some SNFs may consider it burdensome to separate out Medicare beneficiaries from other residents for purposes of submitting the assessments to CMS.

We also note that collecting data on all SNF residents, regardless of their payer, would align our data collection requirements under the SNF QRP with the data collection requirements we have adopted for the LTCH QRP and Hospice QRP.

This proposal, if finalized, would be effective beginning with the FY 2022 program year.

We invite public comment on this proposal.

9. Proposed Policies Regarding Public Display of Measure Data for the SNF QRP

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public after ensuring that SNFs have the opportunity to review their data prior to public display. Measure data are currently displayed on the Nursing Home Compare website, an interactive web tool that assists individuals by providing information on SNF quality of care. For more information on Nursing Home Compare, we refer readers to the website at *https://www.medicare.gov/nursinghomecompare/search.html.* For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

In this proposed rule, we are proposing to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure beginning CY 2020 or as soon as technically feasible. We finalized the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure in the FY 2017 SNF PPS final rule (81 FR 52034 through 52039).

Data collection for this assessment-based measure began with patients admitted and discharged on or after October 1, 2018. We are proposing to display data based on four rolling quarters, initially using discharges from January 1, 2019 through December 31, 2019 (Quarter 1 2019 through Quarter 4 2019). To ensure the statistical reliability of the data, we are proposing that we would not publicly report a SNF's performance on the measure if the SNF had fewer than 20 eligible cases in any four consecutive rolling quarters. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states, ''The number of cases/resident stays is too small to publicly report''. We invite public comment on our proposal.

B. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

1. Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, and adopted policies on performance standards, performance scoring, and sought comment on an exchange function methodology to translate SNF performance scores into value-based incentive payments, among other topics. In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments. Additionally, in the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.

The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. We believe the implementation of the SNF VBP Program is an important step towards transforming how care is paid for, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410). We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51986 through 52009) for discussion of the policies that we adopted related to the potentially preventable hospital readmission measure, scoring, and other topics. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36608 through 36623) for discussions of the policies that we adopted related to value-based incentive payments, the exchange function, and other topics. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), where we adopted a corrections policy for numerical values of performance standards, a scoring adjustment for low-volume facilities, and addressed other topics.

2. Measures

a. Background

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the

SNFRM as soon as practicable, as required by statute.

b. SNFPPR Update—Change of Measure Name

In the FY 2017 SNF PPS final rule (81 FR 51987 to 51995), we adopted the SNFPPR as the SNF all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF VBP Program to meet the requirements in section 1888(g)(2) of the Act. This claims-based measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for SNF patients within 30 days of discharge from a prior admission to an Inpatient Prospective Payment System (IPPS) hospital, CAH, or psychiatric hospital. However, we have not yet transitioned the SNF VBP Program to using the SNFPPR.

The SNFPPR is one of two potentially preventable readmission measures specified for use in the SNF setting. The SNFPPR is specified for use for the SNF VBP Program and a second measure, the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program, is specified for use in the SNF QRP. While these two measures are aligned in terms of exclusion criteria and risk adjustment approach, they differ in their readmission windows. The SNFPPR utilizes a 30-day post-hospital discharge readmission window whereas the SNF QRP potentially preventable readmission measure utilizes a 30-day post-SNF discharge readmission window, consistent with the discharge readmission window specified in other measures we have developed with respect to domains described in section 1899B of the Act, such as the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility QRP and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health QRP.

As described in the FY 2017 SNF PPS final rule (81 FR 51992), our rationale for having two different measures was that the readmission window associated with each measure assesses different aspects of SNF care. The readmission window for the SNFPPR measure was developed to align with the SNFRM which was previously adopted for the SNF VBP Program. Both the SNFRM and SNFPPR measure specifications, including the readmission window, were designed to harmonize with CMS's Hospital Wide All-Cause Unplanned Readmission (HWR) measure used in the Hospital IQR Program. The advantage of this window is that it assesses readmissions both during the SNF stay and post-SNF discharge for most SNF patients, depending on the SNF length of stay (LOS).

The readmission window used for the SNF QRP measure aligns with the readmission window used in other readmission measures for post-acute care (PAC) providers. The focus of this post-PAC only discharge readmission window is on assessing potentially preventable hospital readmissions during the 30 days after discharge from the PAC provider.

While the SNFPPR and the SNF QRP potentially preventable readmission measures assess different aspects of SNF care, we have received stakeholder feedback that having two SNF potentially preventable readmission measures has caused confusion. To minimize the confusion surrounding these two different measures, we are changing the name of the SNFPPR to Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge. We believe this new measure name will clearly differentiate the SNF VBP potentially preventable readmission measure from the SNF QRP potentially preventable readmission measure, thereby reducing stakeholder confusion. We intend to submit the SNFPPR measure, hereafter referred to as the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure, to the National Quality Forum (NQF) for endorsement review as soon as that is feasible.

3. FY 2022 Performance Period and Baseline Period and for Subsequent Years

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. Based on those considerations, as well as public comment, we adopted CY 2017 as the performance period for the FY 2019 SNF VBP Program, with a corresponding baseline period of CY 2015.

Additionally, in the FY 2018 SNF PPS final rule (82 FR 36613 through 36614), we adopted FY 2018 as the performance period for the FY 2020 SNF VBP Program, with a corresponding baseline period of FY 2016. We refer readers to that rule for a discussion of the need to shift the Program's measurement periods from the calendar year to the fiscal year. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), where we adopted FY 2019 as the performance period for the FY 2021 program year, with a corresponding baseline period of FY 2017. In that final rule, we also adopted a policy where we would adopt for each program year a performance period that is the 1-year period following the performance period for the previous program year. We adopted a similar policy for the baseline period, where we stated that we would adopt for each program year a baseline period that is the 1-year period following the baseline period for the previous year.

Under this policy, the performance period for the FY 2022 program year will be FY 2020, and the baseline period will be FY 2018.

4. Performance Standards

a. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy, as well as the numerical values for the achievement threshold and benchmark for the FY 2019 program year. We also responded to public comments on these policies in that final rule.

We published the final numerical values for the FY 2020 performance standards in the FY 2018 SNF PPS final rule (82 FR 36613) and published the final numerical values for the FY 2021 performance standards in the FY 2019 SNF PPS final rule (83 FR 39276). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

b. FY 2022 Performance Standards

As we discuss in this proposed rule, we will adopt FY 2018 as the baseline period for the FY 2022 program year under our previously-adopted policy of advancing the performance and baseline period for each program year automatically.

Based on the baseline period for the FY 2022 program year, we are estimating that the performance standards would have the numerical values noted in Table 14. We note that these values represent estimates based on the most recently-available data, and we will update the numerical values in the FY 2020 SNF PPS final rule.

TABLE 14—ESTIMATED FY 2022 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79476	0.83212

5. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program, along with responses to public comments on our policies and examples of scoring calculations. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted, our request for comments on SNFs with zero readmissions, and our request for comments on a potential extraordinary circumstances exception policy.

We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted (1) A scoring policy for SNFs without sufficient baseline period data, (2) a scoring adjustment for low-volume SNFs, and (3) an extraordinary circumstances exception policy.

We are not proposing any updates to SNF VBP scoring policies in this proposed rule.

6. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

For estimates of FY 2020 SNF VBP Program incentive payment multipliers, we encourage SNFs to refer to FY 2019 SNF VBP Program performance information, available at: *https://data.medicare.gov/Nursing-Home-Compare/SNF-VBP-Facility-Level-Dataset/284v-j9fz.* Our analysis of historical SNF VBP data shows that the Program's incentive payment multipliers appear to be relatively consistent over time. As a result, we believe that the FY 2019 payment results represent our best estimate of FY 2020 performance at this time.

We are not proposing any updates to SNF VBP payment policies in this proposed rule. However, for the reader's information, we modeled the estimated impacts of the low-volume adjustment policy that we established in the FY 2019 SNF PPS final rule for FY 2020 and estimate that the application of the low-volume adjustment policy to the FY 2020 program year would redistribute an additional $8.1 million to these low-volume SNFs for that program year. This would increase the 60 percent payback percentage for FY 2020 by approximately 1.51 percent, resulting in a payback percentage for FY 2020 that is 61.51 percent of the estimated $534.1 million in withheld funds for that fiscal year.

7. Public Reporting on the Nursing Home Compare Website

a. Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF Performance Scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF Performance Scores and the number of SNFs receiving value-based incentive payments, and the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP Program. We also sought and responded to public comments on issues that we should consider when posting performance information on Nursing Home Compare or a successor website. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF measure performance information under the SNF VBP Program on Nursing Home Compare after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Corrections process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and stakeholders with the necessary information to evaluate SNFs' performance under the Program.

b. Public Reporting of SNF Performance Scores, Achievement and Improvement Scores, and Ranking

As we have considered issues associated with public reporting of SNFs' performance information on the Nursing Home Compare website, we have identified an issue that we believe warrants additional discussion. Specifically, we are concerned that the performance information available for display for a specific SNF may, as a result of the application of two policies we have finalized for the Program, be confusing to the public. Specifically, SNFs with fewer than 25 eligible stays during the baseline period for a fiscal year will only be scored on achievement and will not have improvement information available for display. In addition, a SNF with fewer than 25 eligible stays during a performance period will receive an assigned SNF performance score for that Program year that results in a value-based incentive payment amount equal to the adjusted federal per diem rate that the SNF would have received for the fiscal year in the absence of the Program.

In these cases, we do not believe it would be appropriate to suppress the SNF's information entirely given the statutory requirements in section 1888(h)(9)(A) of the Act to publicly report SNF-specific information, but we are concerned about publishing performance information that is not

based on enough data to convey a complete and reliable picture of a SNF's performance for the Program year.

Based on these considerations, we propose to suppress the SNF information available to display as follows: (1) If a SNF has fewer than 25 eligible stays during the baseline period for a Program year, we would not display the baseline RSRR or improvement score, though we would still display the performance period RSRR, achievement score and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25 eligible stays during the performance period for a Program year and receives an assigned SNF performance score as a result, we would report the assigned SNF performance score and we would not display the performance period RSRR, the achievement score or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a Program year, we would not display any information for that SNF. Based on historical data, we estimate that approximately 16 percent of SNFs will have fewer than 25 eligible stays during the performance period and similarly approximately 16 percent of SNFs will have fewer than 25 stays in the baseline period for FY 2020.

We believe that this policy will ensure that we publish as much information as possible about the SNF VBP Program's performance assessments while ensuring that the published information is reliable and based on a sufficient quantity of information. We further believe that this policy will provide stakeholders with meaningful information about SNFs' performance under the Program.

We welcome public comment on this proposal.

8. Update to Phase One Review and Correction Deadline

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We explained that we would accept corrections to the quality measure data used to calculate the measure rates that are included in any SNF's quarterly confidential feedback report, and that we would provide SNFs with an annual confidential feedback report containing the performance information that will be made public. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to any quarterly report provided during a calendar year until the following March 31.

However, as we have continued implementation of the SNF VBP Program, we have reconsidered what deadline would be appropriate for the Phase One correction process. Our experience managing the 2019 SNF VBP Program has shown that fewer than 10 facilities submitted sufficient correction information under the Phase One correction process after October 1, 2018 and before March 31, 2019. Additionally, we are concerned about the effects of the March 31 deadline on value-based incentive payment calculations since the deadline is currently 6 months after payment incentives begin. For example, performance score reports for the FY 2019 SNF VBP Program were provided in August 2018 and incentive payments for that FY were made beginning with services provided on October 1, 2018, but SNFs still had until March 31, 2019 to make a correction. We believe that the March 31 deadline also creates uncertainty for SNFs because, as shown above in the timeline that applied to the FY 2019 Program, their payment incentives could potentially change 6 months after they take effect. If we approve a correction request, we then need to reprocess several months of claims for the SNF in question and potentially need to adjust the exchange function for the fiscal year depending on the scope of the correction and its effects on the payback percentage pool for the fiscal year. We do not believe these outcomes are beneficial to the Program or to SNFs that would have less predictability about their incentive payment percentages for the fiscal year. We believe that the lack of predictability for SNF payment percentages might adversely impact SNF financial planning because payment amounts would not be set for all SNFs until after the March 31 deadline.

We believe that we can mitigate this uncertainty by adopting a 30-day deadline for Phase One correction requests, and note that this proposal would align the Phase One review and correction process with the Phase Two process. Under current operations, we issue a report in June that contains all of the underlying claim information used to calculate the measure rate for the program year, as well as the measure rate itself. We are proposing that SNFs would have 30 days from the date that we issue that report to review the claims and measure rate information and to submit to us a correction request if the SNF believes that any of that information is inaccurate. We note that this proposal would not preclude a SNF from submitting a correction request for any claims for which it discovers an error prior to receiving the June report. However, the 30 day review and correction period would commence on the day that we issue the June report, and a SNF would not be able to request that we correct any underlying claims or its measure rate after the conclusion of that 30 day period.

We are proposing this deadline in lieu of the current March 31 deadline for Phase One corrections. We note that we initially proposed to adopt a 30-day deadline for Phase One corrections in the FY 2017 SNF PPS proposed rule (81 FR 24255), though we finalized a deadline of March 31 following the calendar year in which we provide the report. We adopted that extended deadline to balance our desire to ensure that measure data are sufficiently accurate with SNFs' need for sufficient information with which to evaluate those reports, as well as to provide SNFs with more time to review each quarter's data. In addition, we encouraged SNFs to review the quarterly reports provided with stay-level information and make any corrections to claims before the proposed deadline. However, for the reasons discussed above, we now believe that a 30-day timeframe is sufficient for SNFs to determine if there were errors in its measure calculation by CMS or its contractor.

We believe that this policy will ensure that the underlying claims data that we use to calculate quality measure performance for the SNF VBP Program will be finalized prior to their use in scoring and payment calculations. We believe that this policy will also ensure that any corrections submitted under Phase One do not result in changes to quality measure data months after incentive payment calculations, which will also avoid changes to the exchange function, and as a result, changes to other SNFs' value-based incentive payment percentages for a fiscal year because of data errors for any SNFs. Our experience managing the 2019 SNF VBP Program indicates that very few SNFs would be adversely impacted by the earlier deadline. We also seek to provide SNFs with earlier final annual payment percentage information for their financial planning purposes.

We welcome public comments on this proposal.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 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, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 15 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of the mean hourly wage), and the adjusted hourly wage. The adjusted wage is used to derive this section's average cost estimates.

TABLE 15—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Health Information Technician	29–2071	20.59	20.59	41.18
Registered Nurse	29–1141	35.36	35.36	70.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the mean hourly wage to help estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF Quality Reporting Program (QRP)

The following proposed changes will be submitted to OMB for approval under control number 0938–1140 (CMS–10387). The changes would not impose any new or revised burden. Subject to renewal, the control number is currently set to expire on February 28, 2022. It was last approved on February 12, 2019, and remains active.

The Minimum Data Set (MDS) is part of the process for the clinical assessment of all SNF residents and serves multiple purposes. It is used as a data collection tool for SNFs in the PPS to inform the Patient Driven Payment Model (PDPM) for the purpose of reimbursement, for the SNF QRP for the purpose of monitoring the quality of care in SNFs, and under the requirements of Omnibus Budget Reconciliation Act (OBRA) 1987 for the collection of data for the purposes of comprehensive resident assessment, quality and care planning for SNF residents.

Under sections 4204(b) and 4214(d) of OBRA 1987, requirements related to the submission and retention of resident assessment data are not subject to the PRA. The MDS assessments that are used to inform payment consist of the PPS 5-day assessment, the PPS discharge assessment, and the optional Interim Payment Assessment (IPA). The requirements necessary to administer the payment rate methodology described in 42 CFR 413.337 are subject to the PRA. Thus, the PPS 5-day, PPS discharge, and IPA assessments are subject to the PRA and are active under OMB control number 0938–1140.[193] For the readers' convenience, the active burden estimates are summarized below in Table 16. It is important to note that SNFs currently collect and report data for the SNF QRP through the PPS 5-day and PPS discharge assessments, which are the same assessments used in the PDPM. The IPA is an optional assessment for the PDPM and is not used for the SNF QRP.

Section 2(a) of the IMPACT Act amended the statute by adding section 1899B to the Act, which requires, among other things, SNFs to report standardized patient assessment data, data on quality measures, and data on resource use and other measures. Under section 1899B(m) of the Act, modifications to the SNF assessment instrument, the MDS, required to achieve standardization of patient assessment data are exempt from PRA requirements. However, if the data elements for quality measures and standardized patient assessment data are finalized as proposed, then we believe that we will have met the requirements for standardization of patient assessment data. Therefore, the exemption of the SNF QRP from the PRA is no longer applicable such that the SNF QRP requirements and burden will be submitted to OMB for review and approval. The active ICR serves as the basis for which we now address the previously exempt requirements and burden.

Under our active information collection, only the PPS 5-day and PPS discharge assessments used in the PDPM are also used as the assessments for collecting quality measure and standardized patient assessment data under the SNF QRP. Our active burden sets out 51 minutes (0.85 hours) per PPS 5-day assessment and 51 minutes per PPS discharge assessment. Consistent with the FY 2019 SNF PPS final rule (August 8, 2018; 83 FR 39283) we continue to use the OMRA assessment (with 272 items) to estimate the amount of time to complete a PPS assessment. This is also consistent with our active information collection. In sections VI.A.4 and VI.A.7 of this rule, we propose to add 60.5 items across the PPS 5-day and PPS discharge assessments. Given that the PPS OMRA item set has 272 items (as compared to the PPS discharge assessment with 143 items) that are approved under our active collection, the added items, while increasing burden for each of the assessments, have no impact on our currently approved burden estimates since the active collection uses the PPS

[193] Available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201809-0938-009.*

OMRA item set as a proxy for all assessments. Below, however, we are restating such burden as a courtesy to interested parties.

When calculating the burden for each assessment, we estimate it will take 40 minutes (0.6667 hours) at $70.72/hr for an RN to collect the information necessary for preparing the assessment, 10 minutes (0.1667 hours) at $55.95/hr (the average hourly wage for RN ($70.72/hr) and health information technician ($41.18/hr)) for staff to code the responses, and 1 minute (0.0167 hours) at $41.18/hr for a health information technician to transmit the results. In total, we estimate that it will take 51 minutes (0.85 hours) to complete a single PPS assessment. Based on the adjusted hourly wages for the noted staff, we estimate that it will cost $57.17 [($70.72/hr × 0.6667 hr) + ($55.95/hr × 0.1667 hr) + ($41.18/hr × 0.0167 hr)] to prepare, code, and transmit each PPS assessment.

Based on our most current data, there are 15,471 Medicare Part A SNFs. Based on FY 2017 data, we estimate that 2,406,401 5-day PPS assessments will be completed and submitted by Part A SNFs each year under the PDPM and SNF QRP. We used the same number of assessments (2,406,401) as a proxy for the number of PPS discharge assessments that would be completed and submitted each year, since all residents who require a 5-day PPS assessment will also require a discharge assessment under the PDPM and SNF QRP. We use the Significant Change in Status Assessment (SCSA) as a proxy to estimate the number of IPAs as the criteria for completing an SCSA is similar to that for the IPA. Based on FY 2017 data, 92,240 IPAs would be completed per year under the PDPM.

The total number of PPS 5-day assessments, PPS discharge assessments, and IPAs that would be completed across all facilities is 4,905,042 assessments (2,406,401 + 2,406,401 + 92,240, respectively). The total estimated time for all assessments across all facilities is 4,169,286 hours per year (4,905,042 assessments × 0.85 hours/assessment). For all assessments across all facilities, we estimate a burden of $280,421,251 (4,905,042 assessments × $57.17/assessment).

Given that our proposal to add 60.5 items across the PPS 5-day and PPS discharge assessments is accounted for by using the OMRA assessment as a proxy for all assessments, and given that our estimate for the number of Medicare Part A SNFs and for the number PPS 5-day and PPS discharge assessments completed and submitted by Part A SNFs each year remains unchanged, we are not proposing to revise or adjust any of our active burden estimates. In this regard, we will be submitting a revised information collection request to OMB to account for the added items.

In section VI.A.8.b. of this proposed rule, there are no burden implications associated with updating the data submission system to the iQIES for the SNF QRP once it becomes available, but no later than October 1, 2021. This designation is a replacement of the existing QIES ASAP data submission system and imposes no additional requirements or burden on the part of SNFs.

2. ICRs Regarding the SNF VBP Program

We are not proposing to remove, add, or revise any of our SNF VBP measure-related requirements or burden. Because this proposed rule would not impose any new or revised SNF VBP collection of information requirements or burden, the rule contains no SNF–VBP related collections of information that would be subject to OMB approval under the authority of the PRA.

C. Summary of Proposed Requirements and Annual Burden Estimates

TABLE 16—SUMMARY OF PROPOSED REQUIREMENTS AND ANNUAL BURDEN ESTIMATES UNDER OMB CONTROL NUMBER 0938–1140

[CMS–10387]

Program changes	Number respondents	Responses (per respondent)	Total responses	Time per response (hr)	Total time (hr)	Labor cost per hour ($/hr)	Total cost ($)
Active Burden	15,471	317.04	4,905,042	0.85	4,169,286	varies	280,421,251
Proposed Changes	0	0	0	0	0	0	0
Total	15,471	317.04	4,905,042	0.85	4,169,286	varies	280,421,251

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on our proposed information collection requirements/burden. If you wish to comment, please identify the rule (CMS–1718–P) along with the information collection's CMS ID number (CMS–10387) and OMB control number (0938–1140).

To obtain copies of the supporting statement and any applicable supplementary materials, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB control number, and CMS document identifier to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at 410–786–1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This proposed rule would update the FY 2019 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication

in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach on these issues.

2. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

3. Overall Impacts

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). We estimate that the aggregate impact will be an increase of approximately $887 million in payments to SNFs in FY 2020, resulting from the SNF market basket update to the payment rates. We note that these impact numbers do not incorporate the SNF VBP reductions that we estimate will total $527.4 million in FY 2020. We would note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2019 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2020. The impact to Medicare is included in the total column of Table 17. In updating the SNF PPS rates for FY 2020, we made a number of standard annual revisions and clarifications mentioned elsewhere in this proposed rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this proposed rule applies to SNF PPS payments in FY 2020. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2020 SNF PPS payment impacts appear in Table 17. Using the most recently available data, in this case FY 2018, we apply the current FY 2019 wage index and labor-related share value to the number of payment days to simulate FY 2019 payments. Then, using the same FY 2018 data, we apply the proposed FY 2020 wage index and labor-related share value to simulate FY 2020 payments. We tabulate the resulting payments according to the classifications in Table 17 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2019 payments to the simulated FY 2020 payments to determine the overall impact. The breakdown of the various categories of data Table 17 follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the transition to PDPM. This represents the effect on providers, assuming no changes in behavior or case-mix, from changing the case-mix classification model used to classify patients in a Medicare Part A SNF stay. The total impact of this change is 0.0 percent; however, there are distributional effects of this change.
- The fourth column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is 0.0 percent; however, there are distributional effects of the change.
- The fifth column shows the effect of all of the changes on the FY 2020 payments. The update of 2.5 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 2.5 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 17, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this proposed rule, providers in the urban Pacific region would experience a 1.7 percent increase in FY 2020 total payments.

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TABLE 17: Impact to the SNF PPS for FY 2020

	Number of Facilities FY 2020	PDPM Impact	Update Wage Data	Total Change
Group				
Total	15,078	0.0%	0.0%	2.5%
Urban	10,951	-0.7%	0.0%	1.8%
Rural	4,127	3.7%	0.2%	6.4%
Hospital-based urban	380	10.0%	0.1%	12.6%
Freestanding urban	10,571	-1.0%	-0.1%	1.5%
Hospital-based rural	245	20.4%	0.4%	23.3%
Freestanding rural	3,882	3.1%	0.2%	5.8%
Urban by region				
New England	775	2.0%	-0.5%	4.0%
Middle Atlantic	1,470	-3.1%	-0.2%	-0.8%
South Atlantic	1,868	-0.7%	-0.2%	1.6%
East North Central	2,118	0.1%	0.0%	2.5%
East South Central	536	0.7%	-0.1%	3.1%
West North Central	921	3.8%	0.6%	6.9%
West South Central	1,323	-1.2%	0.3%	1.5%
Mountain	527	0.0%	0.2%	2.7%
Pacific	1,407	-0.9%	0.0%	1.7%
Outlying	6	58.7%	0.1%	61.3%
Rural by region				
New England	126	5.4%	-1.5%	6.3%
Middle Atlantic	194	2.3%	0.1%	4.9%
South Atlantic	462	4.2%	0.3%	7.0%
East North Central	908	3.4%	-0.1%	5.8%
East South Central	452	2.4%	0.4%	5.3%
West North Central	1,020	10.2%	0.5%	13.2%
West South Central	666	-0.4%	0.4%	2.5%
Mountain	207	6.0%	1.2%	9.8%
Pacific	92	1.4%	0.3%	4.2%
Ownership				
For profit	10,729	-0.6%	0.0%	1.9%
Non-profit	3,469	1.5%	0.0%	4.0%
Government	880	4.5%	0.1%	7.2%

Note: The Total column includes the 2.5 percent market basket increase factor. Additionally, we found no SNFs in rural outlying areas.

5. Estimated Impacts for the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

Estimated impacts for the SNF QRP are based on analysis discussed in section VII.B.1. of this proposed rule. The proposed SNF QRP requirements add no additional burden to the active OMB #0938–1140 (CMS–10387).

6. Impacts for the SNF VBP Program

Estimated impacts of the FY 2020 SNF VBP Program are based on historical data and appear in Table 18. We modeled SNF performance in the Program using SNFRM data from CY 2015 as the baseline period and CY 2017 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we note that the 60 percent payback percentage for FY 2020 will adjust to account for the low-volume scoring adjustment that we adopted in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). Based on the 60 percent payback percentage (as modified by the low-income scoring adjustment), we estimate that we will redistribute approximately $320.4 million in value-based incentive payments to SNFs in FY 2020, which means that the SNF VBP Program is estimated to result in approximately $213.6 million in savings to the Medicare Program in FY 2020. We refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39280) for additional information about payment adjustments for low-volume SNFs in the SNF VBP Program.

Our detailed analysis of the impacts of the FY 2020 SNF VBP Program follows in Table 18.

TABLE 18: Estimated SNF VBP Program Impacts for FY 2020

Characteristic	Number of facilities	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total incentive payment
Group					
Total	15,421	19.42	37.2169	0.99309	100.00
Urban	11,007	19.47	36.1519	0.99262	85.16
Rural	4,414	19.31	39.8729	0.99426	14.84
Hospital-based urban	355	19.08	42.6453	0.99546	2.14
Freestanding urban	10,602	19.48	35.9056	0.99251	82.98
Hospital-based rural	246	18.98	46.9882	0.99756	0.57
Freestanding rural	3,943	19.32	39.3322	0.994	14.11
Urban by region					
New England	786	19.54	33.0786	0.99119	5.75
Middle Atlantic	1,473	19.25	38.8823	0.99365	15.92
South Atlantic	1,869	19.56	35.6803	0.99256	17.39
East North Central	2,122	19.52	34.5595	0.99174	14.08
East South Central	551	19.69	32.2849	0.99095	3.68
West North Central	923	19.46	36.7211	0.99281	4.01
West South Central	1,336	19.84	31.4446	0.99065	7.32
Mountain	530	18.92	44.5446	0.99634	3.63
Pacific	1,411	19.20	40.4522	0.99475	13.36
Outlying	6	19.38	41.5899	0.99252	0.00
Rural by region					
New England	134	19.12	39.8964	0.99396	0.67
Middle Atlantic	214	19.14	40.4625	0.99406	0.86
South Atlantic	493	19.42	36.8815	0.99294	2.22
East North Central	931	19.15	40.6763	0.99452	3.43
East South Central	520	19.60	34.5229	0.99178	2.31
West North Central	1,064	19.14	44.0171	0.99615	1.93
West South Central	738	19.85	33.6008	0.99171	2.16
Mountain	222	18.78	49.4262	0.99862	0.65
Pacific	97	18.30	55.1379	1.00141	0.62
Outlying	1	18.98	37.0195	0.98788	0.00
Ownership					
Government	982	19.11	43.3338	0.99568	3.70
Profit	10,810	19.52	35.3904	0.99229	75.38
Non-Profit	3,629	19.20	41.0027	0.99478	20.92

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7. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2020 under the SNF PPS will be an increase of approximately $887 million in payments to SNFs, resulting from the SNF market basket update to the payment rates.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

8. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 19 and 20, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule for FY 2020. Tables 17 and 19 provide our best estimate of the possible changes in Medicare payments under the SNF PPS

as a result of the policies in this proposed rule, based on the data for 15,078 SNFs in our database. Tables 18 and 20 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies in this proposed rule.

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2019 SNF PPS FISCAL YEAR TO THE 2020 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$887 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

*The net increase of $887 million in transfer payments is a result of the market basket increase of $887 million.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2020 SNF VBP PROGRAM

Category	Transfers
Annualized Monetized Transfers	$320.4 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

*This estimate does not include the two percent reduction to SNFs' Medicare payments (estimated to be $527.4 million) required by statute.

9. Conclusion

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2020 are projected to increase by approximately $887 million, or 2.5 percent, compared with those in FY 2019. We estimate that in FY 2020 under PDPM, SNFs in urban and rural areas will experience, on average, a 1.8 percent increase and 6.4 percent increase, respectively, in estimated payments compared with FY 2019. Providers in the urban Outlying region will experience the largest estimated increase in payments of approximately 61.3 percent. Providers in the urban Middle Atlantic region will experience the largest estimated decrease in payments of 0.8 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's website at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This proposed rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the aggregate impact for FY 2020 will be an increase of $887 million in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 18 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2020 wage indexes, PDPM transition and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2019 Report to Congress (available at *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf*), MedPAC states that Medicare covers approximately 11 percent of total patient days in freestanding facilities and 19 percent of facility revenue (March 2019 MedPAC Report to Congress, 197). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 18. As indicated in Table 18, the effect on facilities is projected to be an aggregate positive impact of 2.5 percent for FY 2020. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities for FY 2020.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 an MSA and has fewer than 100 beds. This proposed rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals will be a positive impact. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2019 (83 FR 39288)), the category of small rural hospitals is included within the analysis of the impact of this proposed rule on small entities in general. As indicated in Table 18, the effect on facilities for FY 2020 is projected to be an aggregate positive impact of 2.5 percent. As the overall

impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals for FY 2020.

C. Unfunded Mandates Reform Act Analysis

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 2019, that threshold is approximately $154 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is not subject to the requirements of E.O. 13771 because it is expected to result in no more than de minimis costs.

F. Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

G. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review the proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $429.52 (4 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $124,561 ($429.52 × 290 reviewers).

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.30 [Amended]

■ 2. Section 409.30 is amended in the introductory text by removing the phrase ''the 5-day assessment'' and adding in its place the phrase ''the initial patient assessment''.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 4. Section 413.343 is amended by revising paragraph (b) to read as follows:

§ 413.343 Resident assessment data.

* * * * *

(b) *Assessment schedule.* In accordance with the methodology described in § 413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of an initial patient assessment no later than the 8th day of posthospital SNF care and such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.

* * * * *

■ 5. Section 413.360 is amended by revising paragraphs (a) and (d)(1) and (4) to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the SNF as operating in the CMS designated data submission system. For purposes of this section, a program year is the fiscal year in which the market basket percentage described in § 413.337(d) is reduced by two percentage points if the SNF does not

report data in accordance with paragraph (b) of this section.

* * * * *

(d) * * *

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

* * * * *

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

* * * * *

Dated: March 26, 2019.

Seema Verma

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–08108 Filed 4–19–19; 4:15 p.m.]

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Part V

Environmental Protection Agency

40 CFR Parts 704, 711, and 712
TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a); Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704, 711, and 712

[EPA–HQ–OPPT–2018–0321; FRL–9982–16]

RIN 2070–AK33

TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Toxic Substances Control Act (TSCA) section 8(a) Chemical Data Reporting (CDR) requirements and the TSCA section 8(a) size standards for small manufacturers. The current CDR rule requires manufacturers (including importers) of certain chemical substances listed on the TSCA Chemical Substance Inventory (TSCA Inventory) to report data on chemical manufacturing, processing, and use every 4 years. EPA is proposing several changes to the CDR rule to make regulatory updates to align with new statutory requirements of TSCA, improve the CDR data collected as necessary to support the implementation of TSCA, and potentially reduce burden for certain CDR reporters. Proposed updates to the definition for small manufacturers, including a new definition for small governments, are being made in accordance with TSCA section 8(a)(3)(C) and impact certain reporting and recordkeeping requirements for TSCA section 8(a) rules, including CDR. The definitions may reduce burden on chemical manufacturers by increasing the number of manufacturers considered small. Overall, these regulatory modifications may better address EPA and public information needs by providing additional information that is currently not collected; improve the usability and reliability of the reported data; and ensure that data are available in a timely manner.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0321, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susan Sharkey, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8789; email address: *sharkey.susan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute at 15 U.S.C. 2602(9) to include import) chemical substances, including chemical users or processors who may manufacture byproduct chemical substances, and are therefore subject to either of the following: (1) Reporting under the TSCA Chemical Data Reporting (CDR) requirements at 40 CFR part 711 or (2) TSCA reporting and recordkeeping requirements at 40 CFR part 704 or other TSCA reporting requirements which reference the small manufacturer standards at 40 CFR 704.3. Any use of the term ''manufacture'' in this document will encompass ''import,'' the term ''manufacturer'' will encompass ''importer,'' and the term ''chemical substance'' will encompass ''byproduct chemical substance,'' unless otherwise stated.

The regulated community consists of entities that produce domestically or import into the United States chemical substances listed on the TSCA Inventory. The Agency's previous experience with TSCA section 8(a) collections has shown that most respondents affected by this collection activity are from the following North American Industrial Classification System (NAICS) code categories:

- NAICS 325—Chemical Manufacturing; and
- NAICS 324—Petroleum and Coal Product Manufacturing.

In addition to the anticipated respondents from the NAICS listed previously, the regulated community consists of manufacturers of byproducts that are required to report under certain TSCA section 8(a) rules, including CDR. Byproduct manufacturers may be listed under a different primary activity for a site, such as NAICS codes 22, 322, 327310, 331, and 3344 representing, utilities, paper manufacturing, cement manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing, respectively.

The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions at 40 CFR 711.8. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Section 8(a)(1) of TSCA authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may reasonably require (15 U.S.C. 2607). TSCA section 8(a) generally excludes small manufacturers and processors of chemical substances from the reporting requirements established in TSCA section 8(a). However, EPA is authorized by TSCA section 8(a)(3)(A)(ii) to require TSCA section 8(a) reporting from small manufacturers and processors with respect to any chemical substance that is the subject of a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6; that is the subject of an order in effect under TSCA sections 4 or 5(e); that is subject to a consent agreement under TSCA section 4; or that is the subject of relief granted pursuant to a civil action under TSCA section 5 or 7.

TSCA section 8(a)(3)(B) authorizes the EPA Administrator, after consultation with the Administrator of the Small Business Administration (SBA), to prescribe by rule the standards for determining the manufacturers and processors which qualify as small manufacturers and processors. Pursuant

to TSCA section 8(a)(3)(C), on November 30, 2017, EPA determined that revision of the standards is warranted (82 FR 56824).

TSCA section 8(a)(5) requires the EPA Administrator, to the extent feasible, to not require unnecessary or duplicative reporting and minimize the cost of compliance for small manufacturers.

TSCA section 14 imposes requirements for the assertion, substantiation and review of confidential business information (CBI) claims.

C. What action is the Agency taking?

In this action, EPA is proposing several amendments to the current CDR rule requirements. These amendments, described in more detail in Unit III., include:

- Changing requirements for making confidentiality claims, including to identify when upfront substantiation is required, update the substantiation questions, and identify data elements that cannot be claimed as confidential to align with the Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments);
- Replacing certain processing and use codes (industrial function and commercial/consumer product use) with codes based on the Organisation for Economic Co-operation and Development's (OECD) functional use and product and article use codes, including adding reporting of the OECD-based functional use codes for consumer and commercial use information;
- Adding the requirement to report the NAICS code(s) for the site of manufacture;
- Modifying the requirement to indicate whether a chemical is removed from the waste stream and recycled, remanufactured, reprocessed, or reused with the requirement to indicate whether a chemical is removed from the waste stream and recycled;
- Adding a requirement to identify the percent total production volume of a chemical substance that is a byproduct;
- Requiring that the secondary submitter of a joint submission report the chemical specific function along with the percentage of the chemical in the imported product;
- Adding a voluntary data element to provide a public contact;
- Modifying the definition of ''parent company'' to clarify the definition, add the requirement to report a foreign parent company, when applicable, and codify reporting scenarios;
- Simplifying the reporting process for co-manufacturers by enabling a multi-reporter process for reporters to separately report directly to EPA within the e-CDRweb reporting tool;
- Allowing reporting in specified metal categories for inorganic byproducts;
- Adding exemptions for specifically identified byproducts that are recycled in a site-limited, enclosed system and for byproducts that are manufactured as part of non-integral pollution control and boiler equipment; and
- Clarifying regulatory text by removing outdated text, consolidating exemptions, and making other improvements.

Additionally, EPA is proposing an amendment to update the size standards definition for small manufacturers for reporting and recordkeeping requirements under TSCA section 8(a). Further details of this amendment are in Unit IV.

EPA is also giving notice of some aspects of the amendments to TSCA from the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments) that may impact, more broadly, TSCA submitters. For example, under TSCA section 14(e)(1)(B), the Agency is charged with implementing a ten year ''sunset'' provision for confidentiality claims.

Because the small manufacturer size standard under TSCA section 8(a) impacts the CDR rule more than other TSCA section 8(a) reporting rules at this time, EPA included these two actions as one proposed rule. However, EPA recognizes that the changes made to the small business definition will impact current and future TSCA section 8(a) reporting rules and intends to finalize these amendments as two separate actions.

EPA is taking other, non-regulatory steps to minimize the burden on all reporters, including small entities, by improving the reporting application and database to be user-friendly and dynamic, consisting of straightforward questions that include fill-in-the-blank (number) fields, check boxes, and drop-down menus. In addition, EPA is replacing the current pre-formatted Form U with a customized report based on the actual information submitted by a site through e-CDRweb, the electronic reporting tool. Although these changes are not discussed further in this proposal, they are an important component of the effort to reduce burden and modernize the data collection system. EPA is adding an addendum to the current CDR rule ICR (OMB Control Number 2070–0162) for the regulatory changes proposed in this document. In addition to the changes outlined in this proposed rule, if needed, EPA will provide a second addendum to this ICR to address non-regulatory changes. As was done for previous CDR collections, EPA will provide industry with the opportunity to test and comment on the updated e-CDRweb prior to the 2020 CDR submission period. EPA anticipates holding a webinar to introduce the revised e-CDRweb to the regulated community directly following the finalization of the CDR Revisions rule. During the webinar, EPA will issue a general invitation to interested parties to participate in a short testing period of the revised e-CDRweb. EPA will open the testing period within 4 months after this proposal is finalized, and currently anticipates that testing will occur in the February to March 2020 timeframe. Because of resource constraints, the testing period will be limited to 25 participants. For additional information, contact the person under **FOR FURTHER INFORMATION CONTACT**. Also, information will be posted on the CDR website (*https://www.epa.gov/chemical-data-reporting*).

D. Why is the Agency taking this action?

EPA is proposing revisions to the CDR rule for three primary reasons: Align with amendments to TSCA from the Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016 Amendments), improve the CDR data collected as necessary to support the implementation of TSCA, and reduce burden for CDR reporters pursuant to TSCA section 8(a)(5).

The 2016 Amendments to TSCA changed requirements associated with confidentiality claims, including identifying the data elements eligible for confidentiality claims and when substantiation of claims is required. EPA is proposing revisions to the CDR rule to address these changes.

EPA is proposing to modify the definition for small manufacturers, as a result of the 2016 Amendments revision of TSCA section 8(a)(3)(C), which requires EPA, after consultation with the Administrator of the SBA, to review the adequacy of the standards for determining which manufacturers and processors qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). EPA published a determination that revision of the TSCA section 8(a) size standards for small manufacturers as warranted in a **Federal Register** Notice published November 30, 2017 (82 FR 56824). EPA's determination, supporting documents, and comments received can be found at *regulations.gov* under docket number EPA–HQ–OPPT–2016–0675. This proposed change may reduce burden for some manufacturers

that would be considered small manufacturers under CDR and other TSCA section 8(a) rules relying on the small manufacturer definition in 40 CFR part 704.3.

EPA is also proposing to make some changes to the CDR data reporting so the information collected is tailored to better meet the Agency's overall information needs and aligned with specific needs for prioritization and risk evaluation under TSCA section 6. TSCA section 2 specifies that ''adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures'' (TSCA section 2(b)(1)). These proposed changes include the addition of data elements, such as a site-specific NAICS code and how much of a chemical is a byproduct; modification to multi-reporter submission requirements, including adding a process for jointly reporting co-manufactured chemicals; and changes to current data elements, such as codes used for reporting processing and use information. In addition, proposed changes to the parent company reporting requirements would increase EPA's ability to protect confidential information while better enabling EPA to make information publicly available and the addition of a voluntary public contact would direct inquiries from the public to a designated individual rather than to the technical contact. These changes would help to meet the Agency's requirement under TSCA section 26(h), in carrying out TSCA sections 4, 5, and 6, to make scientific decisions consistent with the best available science, improve the CDR data collected as necessary to support the implementation of TSCA, and improve EPA's ability to effectively provide public access to the information. Furthermore, these changes would meet the Agency's objective to obtain new and updated information relating to potential exposures to a major subset of chemical substances listed on the TSCA Inventory.

At the same time, EPA is interested in reducing burden on industry while maintaining the Agency's ability to receive the information it needs to understand exposure to these chemicals (TSCA section 8(a)(5)). EPA used experiences from the 2016 CDR submission period, concerns identified by users of CDR information, and burden-reduction suggestions made as part of public comment opportunities, including public comments solicited in conjunction with Executive Order 13777, *Enforcing the Regulatory Reform Agenda* (EPA–HQ–OA–2017–0190 and 82 FR 17793, April 13, 2017) and as part of the renewal of the Information Collection Request (ICR) (EPA–HQ–OPPT–2017–0648 and 83 FR 36928, July 31, 2018). In addition, EPA identified ways to reduce burden specifically for manufacturers of inorganic byproducts as part of an extensive negotiated rulemaking effort, which included participation by all stakeholder groups, and subsequent public comment period in 2017 (EPA–HQ–OPPT–2016–0597 and 82 FR 47423, October 12, 2017). Taking into account these experiences and stakeholder input, EPA is proposing the following changes to reduce burden: The new ability to alternatively report inorganic byproducts within defined metal categories, the introduction of two new exemptions related to byproducts, a revised approach to reporting for co-manufactured chemicals, and the harmonization of function and product codes with those used by other countries.

Additionally, EPA has received comments that modernizing the CDR data collection and public access to the database would reduce reporting burden and facilitate ease of use by reporters and the public (81 FR 90843; EPA–HQ–OPPT–2016–0597 and Refs. 1, 2, and 3). These comments were used to develop this proposal and to inform other, non-regulatory changes that EPA plans to make to the reporting process.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs and benefits of revising CDR reporting requirements and modifying standards for small manufacturers in CDR and other TSCA section 8(a) reporting. Some aspects of the proposal increase burden and cost while other aspects decrease burden and result in cost savings. Overall, EPA estimates that the combined impact of all the proposed amendments would decrease the total burden and result in a cost savings to industry and government reporters. These analyses, which are available in the docket (Refs. 4 and 5), are discussed in Units III. and IV. and are briefly summarized here.

1. *CDR revisions economic impacts summary.* The proposed amendments are estimated to result in an overall net decrease in burden with associated cost savings. The estimated changes include increases in rule familiarization, compliance determination, and form completion. The future cycle burden and costs or cost savings are listed by type of change:

- For changes to modify or add reportable data elements (*e.g.,* processing and use codes, NAICS codes, byproduct percentage, chemical function, public contact, and parent company—discussed in Units III.B. and III.C.), the incremental burden is expected to increase by 45,000 hours with an associated cost increase of $3.5 million.
- For changes to claiming confidentiality (discussed in Unit III.A.), the incremental burden is expected to decrease by 340 hours with an associated cost savings of $0.03 million.
- For changes to add byproducts exemptions (discussed in Unit III.D.), the incremental burden is expected to decrease by 68,000 hours with an associated cost savings of $5.2 million.
- For changes to implement consolidated category reporting for certain inorganic metals (discussed in Unit III.D.), the incremental burden is expected to decrease by 13,000 hours with an associated cost savings of $1.0 million.
- For changes that affect CDR reporting eligibility (targeted to certain sites with varying reductions to the number of chemicals reported per site), the incremental burden is expected to result in a net decrease by 81,000 hours with associated cost savings at $6.3 million. There are increases in burden and costs for several requirements, such as the need to assess whether exemptions apply (compliance determination) and the need to familiarize oneself with modifications to the rule (rule familiarization), estimated at 3,000 hours with an associated cost of $0.24 million. However, the changes to form completion in the aggregate are estimated to result in an overall net decrease in burden and cost savings due to decreases in the number of sites reporting and or the number of chemical reports from a site. These decreases are due to the proposed byproduct exemptions (discussed in Units III.D.2. and III.D.3.) and consolidated category reporting (discussed in Unit III.D.1.).

In sum, the overall incremental impacts to industry and government reporters result in a net decrease in burden and cost savings. Estimates include rule familiarization, compliance determination, and CDR form completion (Ref. 4). Note that estimated changes to recordkeeping burden and cost are negligible and estimated at zero. An estimated 5,660 sites are expected to report during the next CDR submission period in 2020. The total incremental burden reduction and cost savings are estimated at a 36,000 hour reduction and $2.79 million cost savings. On an annualized basis using a 3 percent and

a 7 percent discount rate over a 10-year period, the annualized incremental cost savings is estimated at $0.66 million and $0.65 million per year, respectively (Ref. 4).

2. *TSCA section 8(a) small manufacturer definition economic impacts summary.* The proposed modified standards for small manufacturers would affect TSCA section 8(a) rules, including CDR. These rules use the TSCA section 8(a) small manufacturer definition to identify the entities exempted from reporting or for other reduced reporting requirements. The impact from the proposal is focused on the CDR rule and may impact whether a site is required to report or the number of chemicals a site would report. There is no measurable impact to other TSCA section 8(a) rules either because EPA has not received any chemical reports for the rule for an extended period of time or because the rule uses a different definition that is not being changed by this proposal (see Unit IV.A. for a more detailed discussion). The proposed definition, discussed in detail in Unit IV., results in a cost savings.

a. *Impact of proposed small manufacturer definition.* The proposal is estimated to eliminate reporting entirely for 93 industry sites and reduce reporting by eliminating the need to report at least one chemical for additional 129 industry sites (Ref. 5). This reduction in reporting is in addition to the sites already not reporting because they meet the current small manufacturer definition.

Under this proposed definition, incremental future cycle burden reductions and cost savings are estimated at 64,000 hours and $5.0 million, respectively, over a four-year CDR reporting cycle (Ref. 5). On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields net annualized incremental cost savings of $1.2 million and $1.2 million per year, respectively (Ref. 5). This proposal also includes a small government exemption (described in this unit).

b. *Impact of proposed small government definition.* The following government entities report under CDR: Seven municipalities, one county-level public utility district, and one tribal entity. Under the proposed small government definition, four government entities would be exempted from the need to report. The burden and cost savings associated with the exempted entities, in future reporting cycles, are included in the estimates for the proposed definition with incremental future cycle burden reduction and cost savings estimated at 500 hours and $39,000 respectively, over a four-year CDR reporting cycle (Ref. 5).

3. *Total economic impacts summary for proposal.* The amendments in this proposal may affect the number of reports submitted during a submission period and the burden to prepare a report. EPA estimates that the combined impact of all the proposed amendments would decrease the total burden and cost to industry associated with CDR reporting. Tables 1A and 1B present the summaries of burden and cost impacts, respectively, for the proposed CDR revisions and TSCA section 8(a) small manufacturer definition update. In the tables, estimates are presented for the CDR four-year first cycle and in the future cycle. In the first cycle, higher burdens and costs are incurred, because all reporters need to familiarize themselves with the changes and may take longer to complete reporting activities. After the first cycle, and for future cycles, experienced reporters (85%) are familiar with the changed requirements. In addition to estimates that cover the four-year CDR cycle, Tables 1A and 1B present annual estimates. These annual estimates are the four-year estimates divided by four. EPA acknowledges that activities may be spread unevenly across the four years. On an annualized basis, using a 3 percent and 7 percent discount rate over a 10-year period yields a net annualized incremental cost savings of $1.85 million and $1.83 million per year, respectively, for the overall proposed rule.

TABLE 1A—SUMMARY OF ECONOMIC IMPACTS, BURDEN REDUCTIONS

	Number of affected sites	First cycle		Future cycles	
		Four-year cycle	Annual	Four-year cycle	Annual
		Burden reduction (hours)	Burden reduction (hours)	Burden reduction (hours)	Burden reduction (hours)
CDR Revisions	5,660	31,306	7,827	36,005	9,001
8(a) Small Manufacturer Exemption [1]	5,627	56,162	14,040	64,295	16,074
Small Government Exemption [2]	33	454	113	504	126
Net Incremental Change	5,660	87,922	21,980	100,804	25,201

General Note: Annual estimates are based on changes applied evenly across the four-year cycle. However, due to rounding issues, results may not be readily derived using this table.

Footnotes:

[1] Under the proposed exemptions, incremental changes represent the net change due to the proposed rule and therefore include sites and chemical reports that are exempted. Note that sites and reports can be entirely affected or undergo a split effect, with a portion of the site's chemical reports exempted.

[2] Four small governments are identified to qualify for the small government exemption under the proposed small government exemption.

TABLE 1B—SUMMARY OF ECONOMIC IMPACTS, COST SAVINGS

	Number of affected sites	First cycle		Future cycles	
		Four-year cycle	Annual	Four-year cycle	Annual
		Cost savings (2017$)	Cost savings (2017$)	Cost savings (2017$)	Cost savings (2017$)
CDR Revisions	5,660	$2,428,630	$607,157	$2,792,871	$698,218
8(a) Small Manufacturer Exemption [1]	5,627	4,357,362	1,089,341	4,988,270	1,247,068
Small Government Exemption [2]	33	35,132	8,783	39,025	9,756
Net Incremental Change	5,660	6,821,124	1,705,281	7,820,166	1,955,042

General Note: Annual estimates are based on changes applied evenly across the four-year cycle. However, due to rounding issues, results may not be readily derived using this table.

Footnotes:

[1] Under the proposed exemptions, incremental changes represent the net change due to the proposed rule and therefore include sites and chemical reports that are exempted. Note that sites and reports can be entirely affected or undergo a split effect, with a portion of the site's chemical reports exempted.

[2] Four small governments are identified to qualify for the small government exemption under the proposed small government exemption.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.*

II. Background

A. What is the Chemical Data Reporting (CDR) rule?

The CDR rule requires U.S. manufacturers of certain chemicals listed on the TSCA Inventory to report to EPA every four years the identity of chemical substances manufactured for all years since the last principal reporting year. For example, for the 2020 submission period, the principal reporting year is 2019 and the last principal reporting year for the 2016 submission period was 2015. Reporting during the 2020 submission period covers the manufacture of chemicals in 2016, 2017, 2018, and 2019. To help minimize reporting burden, detailed information is required only for the principal reporting year (*i.e.,* 2019), including a breakout of the production volume to provide separate volumes for domestically manufactured and imported amounts. Generally, reporting is required for substances whose production volumes are 25,000 pounds or more at any single site during any of the calendar years since the last principal reporting year. However, a lower threshold applies for chemical substances that are the subject of certain TSCA actions (see 40 CFR 711.8(b)). The CDR regulation generally excludes several groups of chemical substances from its reporting requirements, *e.g.,* polymers, microorganisms, naturally occurring chemical substances, certain forms of natural gas, and water (see 40 CFR 711.5 and 711.6). For the 2016 CDR, EPA received Form U's from 5,660 sites with an associated 42,464 chemical reports, providing information on 8,717 unique chemicals.

Persons domestically manufacturing or importing chemical substances are required to report information such as company name, site location and other identifying information, production volume of the reportable chemical substance, and exposure-related information associated with the manufacture of each reportable chemical substance, including the physical form and maximum concentration of the chemical substance, the number of potentially exposed workers at the reporting site and certain processing and use information (40 CFR 711.15). The processing and use information that is currently required includes: Process or use category; NAICS code; industrial function category; percent production volume associated with each process or use category; number of sites; number of potentially exposed industrial or commercial workers; and consumer/commercial information such as use category, use in or on products intended for use by children, and maximum concentration. Under CDR, submitters report information to the extent that it is ''known to or reasonably ascertainable'' (40 CFR 711.15), which means ''all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know'' (40 CFR 711.3, referencing 40 CFR 704.3). Reported information can be claimed as confidential (40 CFR 711.30).

B. How are the CDR data used by EPA?

EPA uses the data reported pursuant to the CDR rule to support health, safety, and environmental protection activities related to chemical manufacturing and use. Manufacturing, processing and use information about chemicals in commerce helps EPA understand exposure to these chemicals and screen and prioritize chemicals to identify potential human health and environmental effects. EPA uses the data reported under the CDR rule to support many activities under TSCA and to provide overall support for EPA and other federal, state, local, and tribal health, safety, and environmental protection activities (Ref. 6 and 83 FR 36928, July 31, 2018 (EPA–HQ–OPPT–2017–0648)).

CDR provides basic exposure-related data which EPA uses in a wide variety of its activities, from choosing the chemicals EPA will focus on for prioritization and assessment activities to informing response actions, such as to hurricanes and other disasters. For example, in accordance with TSCA section 6(b)(1)(A), EPA is required to consider ''the conditions of use or significant changes in conditions of use of the chemical substance, and the

volume or significant changes in the volume of the chemical substance manufactured or processed.'' CDR provides information directly pertaining to the conditions of use, such as the number of sites, the number of workers reasonably likely to be exposed, and how and why the chemical is used, based on the CDR processing and use information. In addition, CDR provides the production volume, the production volume over time, and changes in the volumes under different conditions of use. Such information is expected to contribute to improved understanding of the chemical, including during the prioritization process. For example, EPA used the 2012 and 2016 CDR data to assist in identifying current uses and production volumes and, inversely, uses that are no longer ongoing, to help determine the scope of the risk evaluations for the first 10 chemicals being reviewed under amended TSCA. EPA grouped uses for these chemicals based on CDR categories such as industrial, commercial, and consumer use. Additionally, the problem formulations for the first 10 chemicals, which were published in June 2018, used CDR data to identify the number of sites where exposure may occur and approximate workers who may be exposed to the chemicals. For example, in the *Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tertrachloro),* EPA used CDR data to identify conditions of use for Perchloroethylene (Ref. 7). CDR data will continue to inform future prioritization, risk evaluation, and risk management work under TSCA.

For another example, to help prepare EPA and others to respond to hurricane disasters that occurred in 2018, EPA prepared information about chemicals expected to be in the affected areas from data sources such as CDR.

In 2012, EPA published its TSCA Work Plan for Chemical Assessments. CDR data were used extensively in the development of this Work Plan. Using CDR data collected during the 2012 CDR submission period, EPA updated the exposure rankings for the chemicals initially screened as part of the original Work Plan and, in 2014, published a revised Work Plan (2014 Work Plan). TSCA requires that at least 50 percent of all chemical substances undergoing risk evaluation (High-Priority designations) come from the 2014 Work Plan, until the Work Plan chemical list is exhausted.

The Interagency Testing Committee (ITC), an independent advisory committee to the EPA Administrator, uses CDR data when updating the Priority Testing List (PTL). The ITC designates or recommends chemicals to the PTL that the Agency may prioritize when requiring testing under TSCA section 4 or collecting information under TSCA sections 8(a) or 8(d). In making those determinations, production volumes reported to CDR are used to identify the opportunity for exposure to a particular chemical.

OECD member countries develop Emission Scenario Documents (ESD). EPA is an active participant of the OECD Task Force and regularly works on the development of ESDs that are reviewed by the Task Force and added to the published series of ESDs. ESDs developed by EPA cover both occupational exposures and environmental releases due to EPA's review responsibilities under TSCA. In a separate and related effort, EPA has regularly developed industry-specific generic scenarios which are similar to an OECD ESD, as tools to assist in the assessment of the many types of uses for new chemicals reviewed under TSCA. CDR data are used to identify the chemicals commonly used in specific industries, estimate the number of potentially exposed workers, and develop estimates of exposure and releases that support the development of these documents and scenarios.

Additional examples of how EPA uses CDR data include use by the Office of Research and Development to characterize the life cycle of chemicals for life cycle inventories, to develop conceptual models, and to develop standardized emission and release estimates from chemical production. The Office of Water uses CDR data to identify facilities in specific industry sectors while developing effluent guidelines and to identify chemicals of interest and their associated processing and use activities for Effluent Guidelines Annual Review Reports.

C. What are the current standards for small manufacturers and processors?

In 1988, EPA established the general TSCA section 8(a) small manufacturer definition for use in other rules issued under TSCA section 8(a), which are codified at 40 CFR 704.3. These are the current standards that apply to CDR:

Small manufacturer or importer means a manufacturer or importer that meets either of the following standards:

1. *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.

2. *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

3. *Inflation index.* EPA must use the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of the rule (*i.e.,* 40 CFR 704), whichever is later. EPA shall provide **Federal Register** notification when changing the total annual sales values.

Pursuant to authority under TSCA section 8(a)(3)(B), certain TSCA section 8(a) rules codify slight variations of the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 (see, *e.g.,* 40 CFR 704.45). There is no general small processor standard, and EPA is not proposing one in this action. However, other rules issued under TSCA section 8(a) establish analogous standards for small processors in those particular rules. See Unit IV.A. for additional discussion.

III. Detailed Discussion of the Proposed Modifications to CDR

A. Changes to Claiming Confidentiality

EPA is proposing changes to requirements related to claiming CDR data as confidential to be consistent with the new statutory requirements in TSCA section 14. TSCA requires the Agency to review and make determinations regarding the validity of confidential claims for information submitted to EPA. EPA estimates that this proposed change would result in a decrease in burden, which is explained in detail in Table 4–14 in the Economic Analysis (Ref. 4).

New statutory provisions that are pertinent to reporting under CDR include the following:

- Under TSCA section 14(c)(3), all claims of confidentiality must be substantiated at the time the information is submitted to EPA, except for those types of information exempt under TSCA section 14(c)(2).
- The submitter must provide a statement supporting the claim, as described in TSCA section 14(c)(1)(B) and must certify that the statement is true and correct, as described in TSCA section 14(c)(5).
- TSCA section 14(b)(3)(B) limits confidentiality claims for reported use information that customarily would be shared with the general public or within an industry or industry sector.
- Under TSCA section 14(e)(1)(B), confidentiality claims on information not described in TSCA section 14(c)(2) expire after ten years, unless a request for extension is submitted and granted.

The proposed amendments to the CDR rule address these new provisions, with the exception of the TSCA section 14(e)(1)(B) CBI expiration provision which while it will impact all TSCA submissions filed after June 22, 2016 does not distinctively impact the CDR data collections.

This preamble discussion also includes information about other provisions of TSCA relating to actions EPA must take, but that do not impact the regulatory text or require specific submitter actions.

1. *Substantiations.* EPA interprets TSCA section 14(c)(3) as requiring substantiations of non-exempt CBI claims at the time the information claimed as CBI is submitted to EPA (82 FR 6522, January 19, 2017). The Agency is proposing to amend the CDR substantiation provisions to require substantiation for all confidentiality claims except for those types of information exempt from substantiation under TSCA section 14(c)(2), which are described later in this unit. Submission of substantiations at the time of assertion of confidentiality enables EPA to fulfill its obligation under TSCA section 14(g) to review all confidentiality claims for specific chemical identity, plus a representative subset (comprising at least 25 percent) of all other non-exempt confidentiality claims.

EPA is proposing revisions to the current substantiation questions in 40 CFR 711.30 and the addition of new substantiation questions to address data elements which, prior to amended TSCA, did not require substantiation at the time of submission. The questions are in the proposed regulatory text at the end of this notice. In addition, Appendix B of the CDR Revisions EA (Ref. 4) provides a summary of the questions prior to the 2016 TSCA Amendments and those that are being proposed in this action (Ref. 4). These questions would facilitate the Agency's implementation of TSCA section 14 and the requirement to review and approve, approve in part, deny in part, or fully deny requests for confidentiality. These CDR-specific questions are designed to encourage thoughtful consideration of the need for confidential treatment, improve the consistency of EPA's review of the responses, and reduce the need for multiple discussions between EPA and the submitter regarding the substantiations that may otherwise hinder the Agency's ability to timely fulfill its review obligations under TSCA.

The questions have been carefully drafted to elicit the required information to allow for a CBI review and determination, without imposing an unnecessary burden. A set of standard questions, set forth in proposed 40 CFR 711.30(b), would apply to all non-exempt CBI claims. These questions generally ask about the impact of disclosure on the submitter's competitive position, whether the information has been made available to others, and the controls used to protect the confidential information. These are similar in concept to questions under the current CDR at 40 CFR 711.30. Additional questions are targeted to specific data elements. For chemical substance identity confidentiality claims, the additional substantiation questions, set forth in proposed 40 CFR 711.30(c), are substantively the same as exist under the current CDR at 40 CFR 711.30(b). An additional question for company, site, and technical contact identity is set forth in proposed 40 CFR 711.30(d). Although substantively the same as exists for site identity substantiations in the current CDR at 40 CFR 711.30(c), it is newly applied to company name and technical contact confidentiality claims. Additional questions for processing and use information are set forth in proposed 40 CFR 711.30(e) and are substantively the same as exist in the current CDR at 40 CFR 711.30(d).

a. Exceptions to the substantiation requirements. TSCA section 14(c)(2) identifies certain information that shall not be subject to substantiation requirements under this rule. This includes:

- Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;
- Marketing and sales information;
- Information identifying a supplier or customer;
- In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents;
- Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article;
- Specific production or import volumes of the manufacturer or processor; and
- Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under TSCA section 5.

EPA believes that the only data elements collected under CDR that may be subject to the TSCA section 14(c)(2) limit on substantiation requirements are: (1) Production volume and (2) supplier information associated with joint submissions, such as supplier identity and details of the full composition of a mixture. However, these two data elements may still be subject to substantiation and CBI review under the circumstances described in TSCA section 14(f).

i. Regarding production volume. EPA is proposing to not require substantiation at the time the claim of confidentiality is made for five production volume data elements (*e.g.,* the volume domestically manufactured in 2019, the volume imported in 2019, and the total production volume for each of the three years 2016 through 2018). For each reported chemical, total production volume is reported for each of the years since the last principal reporting year, except for the current principal reporting year when the production volume is reported as domestically manufactured and imported volumes. As an example, for the 2020 CDR submission period, production volume is collected for the calendar years 2016, 2017, and 2018. For calendar year 2019, the production volume is reported as domestically manufactured and imported volumes. EPA believes that these five data elements are exactly the kinds of specific production or import volumes identified in TSCA section 14(c)(2)(F).

ii. Regarding information associated with a joint submission. Joint

submissions are necessary under limited circumstances. Currently these circumstances are: (1) A company imports a chemical or a mixture under a trade name and the substance identity, or individual components, are not known to the importer or (2) a manufacturer cannot provide the entire chemical identity of a chemical substance it manufactures because the chemical substance is manufactured using a reactant having an identity that the reactant supplier claims as confidential. In these circumstances, the supplier has identified that it will not disclose to the manufacturer (or importer) or does not, itself, know the chemical identity.

A joint submission is a submission started by a primary submitter, typically an importer. The primary submitter provides the trade name of the subject chemical substance or mixture, the name and address of the supplier, and other information as appropriate. Given the requirements of amended TSCA, EPA proposes to require that the primary submitter identify whether the supplier information, including the supplier identity and chemical substance name (trade name) is confidential. Substantiation of the confidentiality claims for this information is not required at the time of submission under the proposed rule because EPA believes it is exempt from substantiation as ''[i]nformation identifying a supplier'' under TSCA section 14(c)(2)(C).

The secondary submitter of the joint submission provides their company name and location, a technical contact, trade name, and chemical identity(ies) and percentage of each chemical substance in the composition of the substance or mixture represented by the trade name. In addition, as explained in Unit III.B.5., EPA proposes to collect the function of each chemical in the mixture. Given the requirements of amended TSCA, EPA is proposing to provide the ability for the secondary submitter to specifically identify whether this information is claimed as confidential. Except for the percentage composition information, which is generally exempt from substantiation pursuant to TSCA section 14(c)(2)(D), all other reported data elements are subject to substantiation at the time the information is submitted.

b. Chemical identity. Only chemical substances listed on the confidential portion of the TSCA Inventory (the Inventory) can be claimed as confidential. This provision is not new and is reflected in the current CDR rule at 40 CFR 711.30(b). Such a confidentiality claim applies to the specific identity of the chemical substance as it is listed on the confidential portion of the Inventory. CDR reported chemical identities, including generic chemical names, that are listed on the public portion of the Inventory cannot be claimed as confidential and would be made publicly available. EPA included this discussion for clarification purposes only and is not proposing any changes to this approach.

c. Connection between company, site, or technical contact identity and chemical-specific information. EPA is proposing to require assertion and substantiation of a claim of confidentiality at the time of submission, on a chemical-specific basis, for the linkage between company or technical contact identity and chemical substance information. This is the same as is currently required under 40 CFR 711.30(c) for site identity, when on a chemical-specific basis, one must claim the linkage between the site identity and the chemical substance information as confidential by asserting and substantiating the claim at the time of submission. There would likely be instances where a confidentiality claim for a company name would not be appropriate, but one for site identity or technical contact might be appropriate.

d. Benefits of proposed changes to CBI substantiation. The reduced amount of information subject to confidentiality limitations will facilitate greater interagency and public sharing of data and will decrease the number of inappropriate or unnecessary claims of confidentiality, which will increase the transparency and public accessibility of the CDR. Clarification of which data elements can be claimed as confidential will improve the consistency of EPA's review of CBI substantiation information and will decrease the need for multiple conversations between EPA and reporters about substantiation responses, thus reducing burden for the Agency and for reporters.

2. *Certification.* The authorized official submitting confidentiality claims must certify all claims for confidentiality are true and correct, and all information submitted to substantiate such claims is true and correct. As required by TSCA sections 14(c)(1)(B) and 14(c)(5). EPA combined these requirements into a single certification statement, which was implemented in the CDR electronic reporting tool in June 2016. EPA is proposing to codify the language of the certification statement in the CDR rule (see the proposed regulatory text for 40 CFR 711.30(h)).

3. *Processing and use data not protected from disclosure.* TSCA section 14(b)(3)(B), as amended by the 2016 Amendments, prohibits confidentiality claims for the following submitted information: ''a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.''

This statutory provision directly impacts and limits confidentiality claims for certain CDR processing and use data. Thus, EPA proposes to codify in the regulatory text that the following data elements cannot be claimed as confidential because they constitute general descriptions of processes and uses that customarily would be shared with the general public or within an industry or industry sector:

- *Certain Industrial processing and use data elements.* The data elements which directly relate to how the chemical is used or processed, *i.e.,* the type of process or use; the industrial sector; and the industrial function (40 CFR 711.15(b)(4)(i)(A), (B), and (C)).
- *Certain Consumer and Commercial use data elements.* The data elements which directly relate to how the chemical is used, *i.e.,* the product category (§ 711.15(b)(4)(ii)(A)); whether the chemical is used in commercial or consumer products (§ 711.15(b)(4)(ii)(B)); whether the chemical is likely to be used in children's products (§ 711.15(b)(4)(ii)(C)); and the function of the chemical in the consumer or commercial product (the function is a proposed data element—see Unit III.B.5. for additional information).

For the purposes of this proposal, EPA believes that other CDR processing and use data elements do not offer a ''general description'' and therefore do not fall within the limits of TSCA section 14(b)(3)(B). Under this proposal, submitters may continue to assert claims of confidentiality for the following processing and use data elements:

- *Certain Industrial Processing and use data elements.* Percent production volume, number of sites, and number of workers (§ 711.15(b)(4)(i)(D), (E), and (F)).
- Certain Consumer and Commercial use data elements. Percent production volume, maximum concentration, and number of commercial workers (§ 711.15(b)(4)(ii)(D), (E), and (F)).

4. *Time duration of confidentiality claims.* In accordance with TSCA section 14(e)(1)(B), non-exempt confidentiality claims are initially protected from disclosure for a period of 10 years from the date of submission and confidentiality assertion, assuming all other relevant requirements of the statute are met. Information on confidential business information under TSCA is available on EPA's website at *https://www.epa.gov/tsca-cbi.* One of the proposed new substantiation questions asks whether the submitter anticipates that the claim's duration would last less than the 10-year statutory time frame. Respondents would indicate when the claim would no longer be needed, and EPA would incorporate the release date into its data system, enabling the information to be made publicly available at that time.

B. Modifications to Reportable Data Elements

1. *Processing and use codes.* The CDR rule requires manufacturers to report industrial, consumer, and commercial processing and use information for chemical substances manufactured during the principal reporting year. EPA is proposing multiple changes to the data elements comprising this processing and use information. Specifically, EPA is proposing to replace the CDR industrial function and commercial/consumer product use codes with OECD function, product, and article use categories and to add OECD function categories for commercial/consumer products. EPA is listing these codes in the CDR instructions, rather than codifying them in the CFR, which would enable EPA to limit the codes to just those considered relevant for CDR reporting, with a catch-all ''non-TSCA'' code for the OECD codes that do not fit under TSCA. EPA would then be able to update the Instructions prior to each CDR submission period to align with any changes to the OECD codes.

EPA did not develop burden estimates associated with replacing the current CDR codes with ones based on the OECD codes because such an estimate heavily relies on the e-CDRweb user interface which will feature burden-reducing guided data entry. The addition of the function categories for commercial/consumer products is a new data element whose addition could potentially result in an increase in burden (not estimated at this time). For additional information, see section 4.1.3.2 in the Economic Analysis (Ref. 4).

The OECD Internationally Harmonized Functional, Product, and Article Use Categories were developed through the OECD Working Party on Exposure Assessment (Task Force on Exposure Assessment) under the leadership of the EPA, based on a review of current functional use and product categories from the United States, Canada, and the European Union; bilateral discussions with the European Chemicals Agency (ECHA); and multiple reviews from task force members. The OECD categories are described in the document ''Internationally Harmonised Functional, Product and Article Use Categories'' (referred to herein as the OECD Category Document) (Ref. 8).

Harmonizing CDR use codes with the OECD codes would expand the utilization of applicable use and exposure-related information from international sources to support EPA risk evaluation and risk assessment activities for new and existing chemicals. Additionally, this harmonization would provide industry with international uniformity in use and exposure information reporting, enabling industry to better streamline their different country-specific reporting requirements.

EPA has received requests to harmonize CDR data categories and descriptions with other countries to the extent possible. In particular, industry stakeholder groups such as the American Chemistry Council have expressed a desire to harmonize with Canadian and OECD data collections in order to provide common global terminology and preciseness in risk evaluation (Ref. 9). EPA worked closely with Canada in the development of the current CDR processing and use codes, and both EPA and Canada were involved in the development of the OECD Harmonized codes.

Under CDR, there are two main categories of use codes: Function use codes and product use codes. The function of a chemical combined with the type of product that the chemical is used in provides an exposure scenario with unique characteristics. These exposure scenarios are necessary for implementation of TSCA for the prioritization of the chemical and for further consideration for the development of exposure and risk evaluations.

a. *Function codes (industrial and consumer/commercial).* EPA currently requires the reporting of function categories for chemical substances used in industrial products but does not require the reporting of a chemical substance's function for commercial/consumer products. EPA is proposing to require reporting of function use categories for both industrial and commercial/consumer products and to adopt the OECD functional use categories.

Function codes are based on the intended physical or chemical characteristic for when a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used (*e.g.,* as an abrasive, a catalyst, or an elasticizer). EPA uses information regarding the function of a chemical substance in combination with the industrial sector and processing or use operation to identify an exposure scenario or the type of application in which a chemical would be used (such as solvents for cleaning and degreasing). Understanding the exposure scenarios or the type of application of the chemical would inform assessment of the potential route, duration, frequency and magnitude of exposure.

During screening and risk evaluation activities, EPA evaluates how the chemical substance is manufactured, processed, distributed in commerce, used, and disposed of. Currently, CDR requires the reporting of consumer and commercial product categories but does not require the reporting of chemical function within the product category. The lack of functional use information for consumer and commercial applications has restricted EPA's ability to provide more complete evaluations or more realistic characterizations of exposure for consumer and commercial applications; instead, EPA relies in many cases on scenarios using potentially conservative assumptions. (Ref. 10) The addition of information on the function of the chemical in combination with the consumer or commercial product category would improve EPA's ability to consider exposures to consumers and in commercial applications, providing a more accurate and real-world understanding of the uses of chemical substances throughout their life cycle.

As explained in the OECD Category Document, the OECD product and article use categories are intended to focus on the end-use application of chemicals within products and articles, rather than upstream manufacturing and processing. However, the functional use categories cover the life cycle and describe the specific function that a chemical provides when used in the formulation of a product or article, or when used within an industrial process. While the function of a chemical may be the same across its life cycle, certain functions may only be appropriate for consideration in an industrial setting,

while others may be relevant for a consumer or commercial setting.

Adopting the OECD functional use codes would provide greater detail by expanding the function categories from the 35 codes currently used by CDR to 117 codes. For example, the broad current CDR category *Adhesives and Sealants* corresponds to four categories under the OECD harmonized codes in this proposal: *Adhesion/Cohesion Promoters, Binders, Flux Agents,* and *Sealants (Barrier).* In this proposed rule, not all of the OECD harmonized codes would be adopted to CDR because some are for uses not covered by TSCA (*e.g.,* in the circumstances where, because of a chemical's particular use, it is not a ''chemical substance'' under TSCA section 3(2)(B)(vi)). The current CDR codes contain a catch-all ''non-TSCA code'' for uses that are not covered under TSCA. Under this proposed rule, EPA would continue to provide the same non-TSCA code as a blanket code for these applications, such as for a food or cosmetic (other than soap), when the chemical is reportable to CDR because the chemical is also used in a way that falls under the jurisdiction of TSCA. EPA is interested in receiving comments on whether all of the OECD harmonized codes should be listed so that the codes are an exact match, even if the uses are not covered by TSCA. Would the exact match make it easier for submitters to report information under CDR and other reporting requirements using the OECD harmonized codes?

EPA is listing these codes in the CDR instructions discussed in Unit III.B.1. Additional details about the proposed function categories, how they are related to the OECD functional use categories, and a crosswalk with the current CDR function codes are in the supplemental document *Technical Support Document: Harmonizing CDR Functional and Product codes with OECD Functional, Product, and Article Codes* (Ref. 11).

b. Commercial/consumer product codes. CDR currently requires the reporting of product category codes for manufactured chemical substances that have consumer or commercial uses. The current product codes consist of both article and other non-article products; they correlate to the OECD Product and Article Use Categories described in the OECD Category document (Ref. 8). The OECD Category document uses the term ''product'' to mean consumable liquids, aerosols, semi-solids, or solids that are used a given number of times before they are depleted and the term ''articles'' to generally mean solids, polymers, foams, metals, and woods, all of which are always present within indoor environments for the duration of their useful life, which may be several years (Ref. 8). These terms were developed for the OECD Category document because, for the purposes of exposure assessment, products and articles are treated differently. Formulations, anticipated use patterns, and available approaches to estimate exposure are different, and certain chemicals may only be added to articles, others only used to formulate products, and others could be used for both. Because of these differences, OECD provides separate lists of product and article use categories. EPA is proposing to adopt the OECD codes and to consolidate the separate OECD lists into one list to be consistent with the current CDR approach of listing the article and other non-article products in one list of CDR Product Categories.

CDR product categories are broader than the OECD categories. Using the OECD categories would provide a specificity that would be more helpful to EPA in carrying out its responsibilities under TSCA. For example, a broad CDR category is *Fuels and Related Products,* which, under the OECD product codes, is divided into three categories: *Cooking and Heating Fuels, Fuel Additives, and Vehicular or Appliance Fuels* (Ref. 11). Under this proposal, the current 33 consumer/commercial product categories would be replaced by 98 categories. For a listing of the proposed product categories, see Appendix D of the Instructions for Reporting (Ref. 12). Under TSCA, the definition of ''chemical substance'' excludes certain uses such as pesticide, tobacco, food, and other specifically listed uses. Some of the OECD harmonized product categories cover the TSCA-excluded uses; those particular codes were not adopted in CDR. The current CDR codes contain a catch-all ''non-TSCA code'' for uses that are not covered under TSCA. Under this proposed rule, EPA would continue to provide the same ''non-TSCA'' code as a blanket code for these applications. EPA is interested in receiving comments on whether all of the OECD harmonized codes should be listed, even if the uses are not covered by TSCA, to make it easier for submitters to report information under CDR and in response to other reporting requirements using the OECD harmonized codes. Additional details about the proposed product categories, how they are related to the OECD product and article categories, and a crosswalk with the current CDR product codes are in the supplemental document *Technical Support Document: Harmonizing CDR Functional and Product codes with OECD Functional, Product, and Article Codes* (Ref. 11).

2. *NAICS codes for manufacturers.* EPA is proposing to require submitters to report the 6-digit NAICS code that best describes the manufacturing activities conducted at the reporting site. The NAICS was developed under the direction and guidance of the Office of Management and Budget (OMB) as the standard for use by Federal statistical agencies in classifying business establishments for the collection, tabulation, presentation, and analysis of statistical data. NAICS is based on a production-oriented concept, meaning that it groups establishments into industries according to similarity in the processes used to produce goods or services (62 FR 17288). Use of the standard provides uniformity and comparability in the presentation and understanding of data. EPA estimates that this proposed change would result in a slight increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

EPA would use the NAICS code information in its analysis of the reported manufacturing-related information to better analyze the data by industry sector. EPA's insight into particular industry sectors has been limited without this particular data element. For example, during the 2017 negotiated rulemaking, participants asked EPA to analyze specific industries to determine if there was overlap in reporting among different Agency programs and to determine if EPA could trace the life cycle of some chemical substances from their manufacture through their use and to their disposal (Refs. 13 and 14). NAICS codes would have better enabled EPA to fulfill the requests because many other EPA programs, such as the Toxics Release Inventory (TRI), require the reporting of NAICS codes. By adding the site's NAICS code as a required data element for CDR, EPA would be better able to use information from CDR in conjunction with TRI data to support implementation of TSCA.

Because reporting under CDR is done by the site that is conducting the manufacturing activity, the site is expected to be sufficiently knowledgeable to be able to determine the appropriate NAICS code. EPA believes sites would be able to identify a single NAICS code per site; however, the Agency is interested in comments on whether the CDR reporting tool should enable the reporting of multiple NAICS codes based on each chemical substance, similar to how the technical contact is reported.

a. Relationship to processing and use industrial sector codes. For processing and use information, often conducted at sites other than the manufacturing site, submitters currently report an industrial sector (IS) code instead of the NAICS codes. The IS codes divide the entire range of NAICS codes into sectors such that there is a sector corresponding to any NAICS code. Initially, submitters reported NAICS codes when describing the industrial processing and use of their reported chemicals. In the 2011 Inventory Update Reporting (IUR) Modifications final rule, EPA replaced the NAICS codes with the industrial sector codes. (76 FR 50816, August 16, 2011; EPA–HQ–OPPT–2009–0187–0393). Respondents to the 2006 IUR, the predecessor to the CDR, submitted 342 unique 5-digit NAICS codes. So many codes made it difficult for EPA to group chemical substances based on industrial processing and use scenarios. In all, the 2006 IUR database has 2,330 unique combinations of processing or use codes, NAICS codes, and industrial function categories. This large number of unique combinations increased the difficulty and time required by EPA to sort and classify chemical substances because EPA either would need to develop exposure scenarios for each unique combination or determine the three-code combinations that have similar exposure scenarios and can be grouped. The use of the IS codes for the 2012 and subsequent CDR reporting cycles has reduced the number of unique combinations, thereby increasing the usability of the data and reducing the associated reporting burden.

EPA believes that the manufacturing of chemicals incorporates a narrower range of NAICS codes than the processing and use of chemicals. Therefore, identifying the more specific NAICS code for the manufacturing site is not expected to result in the large number of combinations experienced in 2006 for the processing and use information.

b. Improving outreach and reporting assistance. EPA would also use the NAICS codes to improve outreach and reporting assistance for manufacturers in specific industry sectors. For the 2016 submission period, EPA developed industry sector-specific Fact Sheets for the printed circuit board, metal mining, and electricity-generating sectors (Refs. 15, 16, and 17). Each Fact Sheet addressed reporting requirements specific to that industry, including the use of specific and unique examples designed to better illustrate the sector's reporting requirements. EPA expects to continue this practice for other industries, and having NAICS codes available in the CDR dataset would facilitate expansion of this outreach.

3. *Modifying recycled information.* Currently, CDR submitters identify whether their reportable chemical substance is *recycled, remanufactured, reprocessed, reused, or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream.* EPA is proposing to modify this data element by removing the terms ''remanufactured, reprocessed, reused'' as this may be interpreted and applied too broadly to obtain the information of interest for this collection. These terms are also not necessarily synonymous with ''recycle'' in all scenarios. It is EPA's intention that this data element identify the chemical substances that would otherwise be disposed of as a waste, and EPA believes the revised phrase ''recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream'' best describes this intention. This proposed change is also intended to reduce confusion, and thus burden, and provide greater specificity as to what this data element requires. For example, the term ''reused'' might cause the site to consider the need to report other chemical substances that it simply purchased and used if the site found a way to reuse that substance. Such reporting would be erroneous, because a site is only required to report a substance that it manufactures, not that it has merely purchased. However, if a manufactured (including imported) substance is reused instead of being disposed of as a waste, then that would be reported. EPA does not anticipate a change in burden associated with this proposed change. See section 4.1.3 of the Economic Analysis for additional information (Ref. 4). EPA is soliciting public comments on modifying this data element to better capture recycling in CDR.

EPA is soliciting comment on whether submitters should identify the percentage of total production volume of their chemical substance that is recycled instead of only designating whether recycling occurred, the burden associated with providing such an estimate, and any difficulties industry might encounter in estimating such a percentage (either to the nearest 10 percent or more accurately). EPA believes that the percent production volume for a chemical substance that is being recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream would be information relevant to the exposure profile of a chemical substance and indicates efficiencies within the chemical manufacturing industry. EPA is interested in the exposures from these activities. In addition, information about whether certain types of industries recycle or whether certain types of chemicals are recycled and if such recycling is increasing or decreasing provides information about changes in the manufacturing environment that inform EPA's TSCA activities. Collecting specific percentages about recycling could give EPA a better understanding of the recycling reporting universe and provide EPA the opportunity to grant more targeted reporting exemptions and burden reduction activities in future reporting cycles.

4. *Percent byproduct.* EPA is proposing to add the requirement to report the *percent total production volume for a chemical substance that is a byproduct.* EPA believes this data element would provide information to better understand the manufacturing of byproduct chemical substances and the impact of current or potential future exemptions to reporting. EPA is interested in this change in order to increase transparency by identifying important submitter subpopulations and their representations in CDR with respect to production volume. EPA estimates that this proposed change would result in an increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

Information about byproduct reporting has been of particular interest due to requirements of the 2016 amendments to TSCA to conduct a negotiated rulemaking for manufacturers of inorganic byproducts. During the deliberations of the negotiated rulemaking committee, EPA was unable to specifically identify, from the CDR data, chemical substances manufactured as byproducts or byproduct manufacturers who would be impacted by changes to the reporting requirements. With the addition of this data element, EPA will be able to identify those manufacturers that recycle portions of their substances or only report to CDR due to their byproduct production. EPA would consequently be better able to understand a larger spectrum of potential exposure scenarios, by improving understanding of the connection between manufacturing and downstream activities for the purposes of substance life cycle assessments and risk evaluation. In addition, EPA would use this information to inform future decisions about potential changes to CDR requirements.

There are situations where the same chemical substance is manufactured both as a primary chemical substance and a byproduct. While this is rare, it is a known occurrence. For example, when commercial stearic acid is manufactured, it is known to contain significant amounts of palmitic acid and oleic acid as byproducts. Such a producer would also be likely to separately manufacture palmitic acid and/or oleic acid as primary chemical products. In this situation, if the palmitic acid that is manufactured as a byproduct is used for a reportable commercial purpose, its volume would be reported along with the volume of palmitic acid that is separately manufactured at the same site and its volume would be counted as the byproduct portion when calculating the percent manufactured as a byproduct. It is important to recognize that an overproduction of the primary manufactured substance does not meet the regulatory definition of a byproduct, and thus is not considered a byproduct for the purposes of CDR, and should not be counted as such when calculating the percent manufactured for this data element.

Reporting in percentages. As with other percentage production volume reporting requirements in the CDR regulation, EPA is proposing to require that the percentages for the percent byproduct be rounded to the nearest 10 percent, unless the percentage is less than 5 percent. EPA would allow the reporting of more specific percent production volumes. In situations where the percentages account for less than 5 percent of the submitter's total production volume for the reportable chemical substance, the submitter would not round off to zero if the production volume attributable to that amount is greater than or equal to 25,000 lbs. (or in an amount of 2,500 lbs. or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)). In such cases, submitters would report the percentage of production volume attributable to that portion to the nearest 1 percent of production volume. This exception to the general rounding off rule is being proposed to differentiate situations where no portion or a very low portion of the chemical substance is a byproduct, to ensure that adequate manufacturing information would be reported for the larger production volume chemical substances. The 25,000 lbs. (or 2,500 lbs.) level was selected for consistency with the current threshold for reporting under CDR. EPA is interested in receiving comment on whether reporting the percent production volume to the nearest 10 percent or 1 percent for 5 percent or below is a lower burden than simply reporting to the nearest 1 percent for any percentage. EPA is interested in the difficulty that industry might encounter in estimating a percentage rounded to the nearest ten percent or a more accurate percentage of byproduct that is produced in the manufacturing process and what challenges industry may encounter in calculating this estimate. EPA is also interested in the burden estimate associated with calculating this data element. EPA is also interested in receiving general comment on the reporting requirements in this proposed rule, including on the effort required by a submitter to provide the percent production volume that is a byproduct.

5. *Chemical specific function for imported mixtures.* EPA is proposing to require the secondary submitter of a joint submission to report the chemical-specific function along with information on chemical composition of the imported product or mixture. A joint submission is most typically used when a substance or a mixture is imported and the supplier does not provide to the importer the specific chemical identity of the substance or substances that comprise the mixture. See Unit III.A. for additional information about joint submissions. Currently, the importer identifies the function of the imported product. In some circumstances, the function of the imported product can be correctly applied to the specific chemical substance. However, in the circumstance where the imported product is a multi-component mixture, applying the function of the imported product to each component of the mixture can result in identifying a function for an individual chemical substance that is not appropriate. For example, a dye or a fragrance that is part of a cleaning mixture should not be identified as a cleaner, but rather as a dye or a fragrance. Providing the appropriate function for the component of the mixture would inform the assessment process by improving the understanding of the conditions of use for a chemical (*e.g.,* formulation, use rate, etc.). EPA does not anticipate a change in burden associated with this proposed change because the burden associated with reporting the function of the chemical for the secondary submitter is already captured in the baseline burden. See section 4.1.3 of the Economic Analysis for additional information (Ref. 4).

6. *Public contact.* EPA is proposing to enable the reporting of a public contact for each CDR submission as a voluntary data element. Currently, a technical contact familiar with the information provided in the form is required to be reported. The public contact would be in addition to the technical contact and would be an individual who may be contacted by the general public with questions related to the publicly available information reported by the company under CDR. This person has been designated by the site or company to handle public inquiries. The addition of a public contact to handle public inquiries is modeled after TRI's approach to the public contact, albeit on a voluntary basis, and would include the contact's name, phone number, and email address. Because the public contact is intended to be made available to the public, this voluntary data element would not be able to be claimed as confidential. EPA is interested in receiving comment on whether it would be helpful to have a public contact available. EPA estimates that this proposed change would result in a slight increase in burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4).

Difference between public contact and technical contact. Submitters to CDR are already required to supply, and may claim as confidential, a technical contact(s) who should be a person able to answer technical questions about the reported chemical substance(s). Typically, a person located at the manufacturing site is best able to answer such questions. The public contact, which would be voluntarily reported, is intended to be a more general, public-facing company representative who would be available to answer questions the public might ask the company.

7. *Parent company identity.* EPA is proposing three changes associated with reporting the parent company under CDR: (1) To add the requirement to report a foreign parent company in addition to reporting the highest-level U.S. parent company when the ultimate parent company is located outside of the United States; (2) to remove the definition of U.S. parent company from 40 CFR 711.3 and replace it with a new definition for parent company; and (3) to add a requirement for reporters to report legal name(s) and to follow a naming convention for providing the parent company name(s), the details of which would be provided in the CDR Instructions (see 40 CFR 711.35). As a whole, EPA believes these changes would increase the usefulness of the CDR data by improving consistency in reporting, better enabling EPA to protect information claimed as confidential, and reducing the after-reporting quality control effort for both EPA and

submitters. EPA estimates that the proposed addition of a foreign parent company would slightly increase the burden, which is explained in detail in Table 4–11 in the Economic Analysis (Ref. 4). EPA did not estimate the burden reduction associated with the reduced need to contact companies for quality control purposes after data submission.

Currently, sites required to report to CDR must report their U.S. parent company, which is defined to mean the highest-level company located in the United States that directly owns at least 50 percent of the voting stock of the manufacturer (see 40 CFR 711.3). The site must report its U.S. parent company name, address, and Dun and Bradstreet D–U–N–S® (D&B) number (see 40 CFR 711.15(b)(2)(i)).

Proposed change to definition of U.S. parent company. EPA is proposing to replace the definition of *U.S. parent company* from 40 CFR 711.3 with a new definition for *parent company* that includes both U.S. and foreign parent companies and provides guidelines for different company structures. In developing this definition, EPA considered solely using the definition of ''parent company'' already found in 40 CFR 704.3, but decided to propose the specifically listed guidelines in the regulatory text for clarity and consistency with other programs. Please review the proposals in the following paragraphs. EPA is requesting comment on this approach.

Proposed reporting of foreign parent company. In some situations, the highest-level parent company is outside of the United States. EPA is proposing that sites also identify the highest-level worldwide parent company, when applicable, and therefore is also adding the requirement to report the *foreign parent company* under 40 CFR 711.15. Under this proposal, reporters would continue to report their U.S. parent company, but also report their foreign parent company if the situation applies.

Including the foreign parent company would increase the ability of EPA to protect information claimed as confidential. Currently, some confidential information may be inadvertently disclosed due to challenges in identifying connections between sites when the parent companies are outside of the United States. EPA takes such relationships into account when aggregating confidential information. By reporting the foreign parent company, EPA would be able to better identify company groupings for data aggregation and, ultimately, protection of information claimed as confidential.

This modification would be responsive to industry concerns expressed during the 2016 CDR submission period with not being able to report their ''true'' parent company when that company is outside of the United States. In many cases, sites know the foreign corporation's name more readily than the U.S. parent company's name.

As opposed to relying exclusively on the foreign parent company (where applicable), EPA is retaining the U.S. parent company reporting requirement to allow EPA to align future CDR collections with historical data; inclusion of the U.S. parent company for 2020 reporting would enable EPA to correlate with past reporting cycles and potentially to increase consistency in reporting among sites associated with the same parent company. Including both the U.S. and the foreign parent companies would provide data users greater flexibility when combining CDR data with data from other sources, some of which are limited to only U.S. information.

Application of parent company definition to different situations. EPA recognizes that there are a variety of ownership situations for manufacturers reporting under CDR. The scenario-specific information listed in this document is based on the guidelines included in the proposed definition and contains additional examples illustrating the application of the proposed parent company definition and reporting requirements. The guidelines include how to populate the U.S. and a foreign parent company data elements. EPA is interested in receiving comments on whether the guidelines and these examples encompass the representative range of scenarios for reporting under CDR, and whether the guidelines included in the proposed definition are sufficient. The examples are as follows:

(1) If the site is entirely owned by a single U.S. company that is not owned by another company, then that single company is the U.S. parent company and there is no foreign parent company.

(2) If the site is entirely owned by a single U.S. company that is, itself, owned by another U.S.-based company (*e.g.,* it is a division or subsidiary of a higher-level company), the highest-level company in the ownership hierarchy is the U.S. parent company. If there is a higher-level parent company that is outside of the United States, the highest-level foreign company in the ownership hierarchy is the foreign parent company.

(3) If the site is owned by more than one company (*e.g.,* company A owns 40 percent, company B owns 35 percent, and company C owns 25 percent of the site), the highest-level U.S. company with the largest ownership interest in the site is the U.S. parent company. Under this scenario, this would be either company A itself (if it doesn't have a U.S.-based parent company), company A's parent, or, if it exists, a single parent company that owns both company B and company C, in which case that single parent company would have the largest ownership interest. If there is a higher-level foreign company in the site's ownership hierarchy, that company is the foreign parent company. There may be the situation where the highest U.S. company is company A's parent company but a foreign company owns both company B and company C. In this situation, the foreign parent company would be the highest-level parent company that owns companies B and C and the U.S. parent company would be the parent company of company A.

(4) If the site is ultimately owned by a 50:50 joint venture or a cooperative, the joint venture or cooperative is its own U.S. parent company. If the site is owned by a U.S. joint venture or cooperative, the highest level of the joint venture or cooperative is the U.S. parent company. If the site is owned by a joint venture or cooperative outside the United States, the highest level of the joint venture or cooperative outside the United States is the foreign parent company.

(5) If the site is entirely owned by a foreign company (*i.e.,* without a U.S.-based subsidiary within the facility's ownership hierarchy), the highest-level foreign parent company is the facility's foreign parent company. In this situation, the U.S. parent company would be the site itself.

(6) If the site is a federally owned, the highest-level federal agency or department is the U.S. parent company.

(7) If the site is owned by a non-federal public entity, that entity (such as a municipality, State, or tribe) is the U.S. parent company.

Proposed use of naming convention. EPA is also proposing to require sites to follow the CDR instructions regarding standardized conventions for the naming of a parent company. These naming conventions address common formatting discrepancies, such as punctuation, capitalization, and abbreviations (*e.g.,* ''Corp'' for ''Corporation''). The use of these naming conventions would reduce the number of inconsistencies with the *Parent Company Name* data field, and thereby would increase the reliability and usability of the data and reduce the associated reporting burden due to the

Agency's need to request corrections from reporting companies.

C. Changes to Reporting Process for Co-Manufactured Chemicals

EPA is proposing to change the method manufacturers use to report co-manufactured chemicals. A co-manufacturing relationship occurs when a chemical substance, manufactured other than by import, is produced exclusively for another person who contracts for such production. To be considered a co-manufacture situation, the producing company produces the chemical substance exclusively for another person (the contracting company) under contract for that production. If the chemical substance is produced for other purposes, then the situation fails this first test of ''co-manufacturing.'' For example, if a company manufactures a chemical for speculative purposes based on expectations of the market, the company is not operating in a co-manufacturing situation. In addition, the other person contracting the manufacture (*i.e.,* the contracting company) specifies the identity of the chemical substance, the total amount produced, and the basic technology for the plant process. This is the second test of ''co-manufacturing.'' To be considered co-manufacturers, both of these tests must be met. See 40 CFR 711.3 (definition of ''manufacture''). Although this proposed change reduces co-manufacturer confusion and addresses other industry concerns, EPA estimates that it would have a minimal impact on the burden and therefore did not include an estimate in the analysis. See section 4.1.3.2 in the Economic Analysis for additional information (Ref. 4).

EPA is avoiding the use of the term toll manufacturer for this proposal and future guidance to add clarity for the co-manufacturing situation. In instructions, guidance, and other communication with submitters, EPA may previously have referred to co-manufacturing as toll manufacturing, and more specifically to the two parties as the contracting manufacturer and the toll manufacturer. Because EPA does not specifically define the term ''toll manufacturer,'' EPA now believes the use of this term may be open to mis-interpretation and it would be clearer to use terms associated with the CDR definition of manufacturer in 40 CFR 711.3. Additionally, EPA believes the chemical industry often refers to toll manufacturing in a more general manner, where both of the tests included in the CDR definition for manufacture are not met. These tests are: (1) The chemical substance is produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process.

Current reporting requirements. Under the current CDR rule, the contracting company and the producing company are jointly responsible for reporting and submitting to CDR. Only one report may be submitted per reportable chemical and per production site. In order to report, the contracting company and the producing company must work together and identify who will submit the report they are both responsible for, to prevent duplicate reporting and ensure both parties have met their reporting obligations.

Pursuant to the CDR definition of ''site'' at 40 CFR 711.3, the site reported is the site of physical manufacture (*i.e.,* the producing company's site). This is true irrespective of whether it is the producing company or the contracting company who completes the report. If both parties fail to report, both the contracting company and producing company are liable.

The companies must designate a single technical contact for the specified chemical(s), who can be an employee of either the contracting company or the producing company (or a consultant). This technical contact should be knowledgeable about the specific chemical and should be the best equipped to answer questions about the certain chemical.

Submitters have identified multiple concerns with the current reporting process for co-manufacturers. Current issues associated with using this method for reporting include:

- The contracting company and producing company are unsure who should be primarily or solely responsible for CDR reporting and are concerned regarding the shared liability.
- The producing company has information (such as the number of workers likely to be exposed) that the contracting company does not have, and the contracting company has information (such as information about the processing and use of the chemical substance) that the producing company does not have. However, when currently completing the CDR chemical report, one company may not be willing to share information it considers confidential with the other company.
- In situations where the producing company is reporting for additional chemical substances, the current co-reporting requirement may result in the need to submit multiple CDR reports for the producing company's site. This created a complicated situation that required special handling and increased confusion and burden for the submitter.

Proposed reporting methodology. EPA is proposing to change the reporting mechanism for co-manufacturers by developing a multi-submitter process, similar to that used by importers, where the contracting company is the primary submitter and the producing company is the secondary submitter. When evaluating the co-manufacturing reporting process, EPA considered industry's desire for a flexible reporting mechanism and the need to protect the confidential information of both the contracting company and the producing company. These considerations were made apparent through documented correspondence between EPA and reporters to the 2016 CDR who were either a contracting company or a producing company regarding issues with the co-manufacturing mechanism. EPA also met with representatives from reporting companies to discuss the co-manufacturing mechanism and the challenges related to coordinating a dual effort between the contracting companies and producing companies during the 2016 reporting period (Ref. 18).

In response, EPA is proposing a new methodology for the 2020 and future reporting cycles. Under this new reporting methodology, the contracting company (as the primary submitter) would have the responsibility to initiate a co-manufacture report that would prompt the reporting requirements for the producing company (as the secondary submitter). The contracting company would start the chemical report for the co-manufactured chemical, identifying the chemical substance and the producing company. The contracting company would then initiate the co-manufacture report using e-CDRweb to send a notification to the producing company. Additionally, the contracting company is responsible for completing the volume manufactured (40 CFR 711.15(b)(3)) and the processing and use-related section (40 CFR 711.15(b)(4)). Upon receipt of the email, the producing company will have the information needed to begin its portion of the co-manufacture report, which would include the manufacturing-related data elements from 40 CFR 711.15(b)(3), including the production volume.

Although the manufacturing information section includes the chemical identity field, it is EPA's belief, based on the two tests for a co-manufacturing situation in which the contracting company specifies the

chemical to be manufactured and the process to be used, that the contracting company would be best situated to complete the chemical identity field. EPA also believes that both parties should report the volume manufactured because both are responsible for reporting other data elements and an associated percent production volume. To ensure the percent production volume is correctly interpreted by both data reporters and data users, the basis for that percent production volume must be known. EPA is interested in receiving comments on whether this split in the data elements is reflective of the knowledge of each party in the co-manufacturing relationship.

This improved reporting mechanism would protect the confidentiality of both the producing company and contracting company by ensuring that the contracting company would not require any potentially confidential information from the part of the producing company. This method also would eliminate confusion between the two involved parties by designating the contracting company as the primary submitter responsible for initiating the reporting process. As with current reporting, both parties would remain liable for reporting the co-manufactured chemical because each party has a portion of the information required under CDR. In addition, this co-manufacture reporting procedure enables the use of one Form U per site, because the contracting company indicates the producing company's site without starting a separate Form U and the producing company completes an independent report for any other, non-co-manufactured chemicals in its own site report.

Alternative reporting methodologies. EPA considered alternatives to the proposed approach for reporting in a co-manufacturing situation. The first alternative would require the producing company (instead of the contracting company) to initiate the reporting and to be primarily liable for reporting. In this alternative, the producing company would initiate reporting via a co-manufacture report and provide the exposure information from the manufacturing site. Using e-CDRweb, the producing company would notify the contracting company of the need to provide the remainder of the information. EPA does not favor this option at this time because it believes that the contracting company is likely to be more knowledgeable about the chemical identity and other information required by CDR and therefore better able to complete the reporting requirements.

The second alternative would be to retain the current reporting mechanism (described in *Current reporting requirements)* where the contracting company and the producing company are jointly responsible for reporting and submitting under CDR. This alternative could include the addition of an indication that the chemical is being co-manufactured and, for the contracting company, the addition of the producing company site location. As is currently the case, only one report may be submitted per reportable chemical and per production site; therefore, the contracting company and the producing company must determine who is responsible to submit the one report to prevent duplicate reporting, and work together to provide a single complete report.

EPA requests comments on the proposed reporting methodology where the contracting company is the primary submitter and on the two alternative reporting scenarios (where the producing company is the primary submitter or retaining the current reporting mechanism without a primary or secondary submitter) for improving the reporting process for co-manufacturing situations. In addition to comments on the general approaches, EPA is interested in comments on the information that should be included on each portion of the co-manufacturing report (for the proposed and first alternative).

Definition of site. EPA is proposing to modify the definition of *site* by replacing the term *toll manufacturer* with the term *producing company.* This change would make terminology consistent between the definitions of *site* and *manufacture.*

Relationship of co-manufacturing to imports. As with the current CDR rule, a co-manufactured chemical substance cannot be an import. Rather, the chemical substance produced via an arrangement with a foreign supplier results in an imported chemical substance, and the U.S. importer alone, as the reporting manufacturer, is responsible for reporting that substance.

D. Reporting of Byproducts

EPA is proposing three changes that directly impact manufacturers of byproduct substances, including inorganic byproducts, to: (1) Allow reporting in metal categories for inorganic byproducts; (2) exempt specifically listed byproducts that are recycled in a site-limited manner; and (3) exempt byproducts manufactured in pollution control and boiler equipment when that equipment is non-integral to the primary manufacturing process. Byproducts are defined at 40 CFR 704.3 to mean a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s). In developing these proposals, EPA relied on information gathered during the negotiated rulemaking process (EPA–HQ–OPPT–2016–0597 and 81 FR 90843, December 15, 2016) and from other public comments (EPA–HQ–OA–2017–0190 and 82 FR 17793, April 13, 2017), with the intent to develop proposals for addressing burden for these byproduct manufacturers while maintaining the information needed by EPA, as described in Unit I.C.

1. *Alternative reporting in metal compound categories for inorganic byproducts.* EPA is proposing to allow, but not require, CDR reporting within defined metal compound categories for certain elemental metals and inorganic metal compounds that are produced as inorganic byproducts. Manufacturers of these inorganic byproducts would have the option to combine and report multiple inorganic byproduct metal substances, that otherwise would be reported individually as listed on the TSCA Inventory, into one or more specifically-listed categories (*e.g.,* Chromium & Chromium Compounds).

If the manufacturer has multiple inorganic byproduct chemical substances to report, they would be able to choose to report some byproduct substances in categories and other different byproduct substances as specific substances. However, the manufacturer would not be able to bifurcate the production volume of the same byproduct chemical substance and report a portion in a category and another portion as a specific chemical substance unless the bifurcation is due to having different metal elements present in the byproduct. Some substances would be required to be reported as listed on the TSCA Inventory and not as part of these metal compound categories, because they are of particular interest to EPA. They are described later in this unit.

EPA believes this proposed method of reporting in categories would simplify reporting and ease reporting burden for manufacturers whose inorganic byproduct metal-containing substances have chemical compositions that are non-specific and difficult to identify, while also providing information that meets EPA's needs. Additionally, because manufacturers would retain the ability to report to CDR by specific substances contained on the TSCA Inventory (as is currently required), manufacturers of these byproduct

substances would have the flexibility to report these substances in the manner that they prefer.

Inorganic metal substances that are manufactured as products and not as byproducts would be ineligible to report within a metal category because these non-byproduct substances are intended products and should be more easily identifiable by their manufacturers.

EPA has the explicit authority under TSCA section 26(c) to take any actions authorized or required by TSCA with respect to categories of chemical substances, and the Agency has experience assessing chemicals in categories under TSCA. For an example of how EPA could use information reported in metal compound categories, see the Antimony Trioxide (ATO) Risk Assessment conducted in 2014 (Ref. 19). Because ATO is not specifically listed on the TRI, releases reported under the broader category of antimony compounds were used as a surrogate to evaluate the potential for aquatic exposures.

The proposed defined inorganic metal compound categories are designed in part to allow CDR reporting to align more closely with those chemical substances and compound categories on the 2014 Update to the TSCA Work Plan for Chemical Assessments.

TRI also uses a similar option of reporting under compound categories, many of which are metals. EPA recognizes that many companies report to both statutory programs and is interested in aligning TRI and CDR to the extent possible and reasonable given the differing purposes of the two rules.

The proposed CDR metal categories list is comprised of the following categories from the 2014 Update to the TSCA Work Plan for Chemical Assessments and from TRI (Refs. 20 and 21). In the future, EPA may modify, by rulemaking, the metal categories list as more chemicals are evaluated as part of the existing chemical program:

- Antimony & Antimony Compounds
- Arsenic & Arsenic Compounds
- Barium & Barium Compounds
- Beryllium & Beryllium Compounds
- Cadmium & Cadmium Compounds
- Chromium & Chromium Compounds
- Cobalt & Cobalt Compounds
- Copper & Copper Compounds
- Lead & Lead Compounds
- Manganese & Manganese Compounds
- Mercury & Mercury Compounds
- Molybdenum & Molybdenum Compounds
- Nickel & Nickel Compounds
- Selenium & Selenium Compounds
- Silver & Silver Compounds
- Thallium & Thallium Compounds
- Vanadium & Vanadium Compounds
- Zinc & Zinc Compounds

To better characterize which substances would be reportable within these metal compound categories, EPA is proposing to use the definition of inorganic chemical substances that was originally part of the IUR (51 FR 113, June 12, 1986). For the purposes of this rule, inorganic substances would be defined to mean those substances that do not contain carbon or contain carbon only in the form of carbonato [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups (*e.g.,* thiocarbonato (=CS3-xOx, where x = 0–2), thiocyanato (-SCN), or isothiocyanato (-NCS)). It should be noted that EPA does not consider organometallics to be inorganic chemical substances, and therefore such substances would not be reportable under metal compound categories. Examples of organometallic substances listed on the TSCA Inventory are: Ferrocene, benzoyl- (CASRN 1272–44–2), Plumbane, tetraethyl- (CASRN 78–00–2), Stannane, tetrabutyl- (CASRN 1461–25–2), Mercury, dimethyl- (CASRN 593–74–8), and Cobalt, di-.mu.-carbonylhexacarbonyldi-, (Co-Co) (CASRN 10210–68–1).

As an example of how to use this inorganic metal compound category reporting method, a manufacturer who is domestically producing Copper chloride, Copper hydroxide, and Copper sulfide as byproduct substances would have the option to report all of these inorganic byproducts under a single report of Copper and Copper compounds, aggregating their volumes. If reporting by category, the manufacturer in this example would first assess if it meets the threshold for reporting by combining the production volumes for all three substances (Copper chloride, Copper hydroxide, and Copper sulfide). If the combined threshold for *any* of the years since the last principal reporting year is 25,000 lbs. or greater, the manufacturer has met the reporting threshold for the copper compound category (*e.g.,* for 2020 CDR, consider the production volumes for 2016, 2017, 2018, and 2019), which would prompt the need for the manufacturer to report for that category of chemicals (Ref. 22).

In terms of reporting, however, EPA is proposing that only the *weight* of the parent metal portion of the metal category compound would be reported (for example, if reporting by categories, 34,000 pounds of Copper chloride (CuCl2) (CASRN 7447–39–4) would be reported based on 16,072 pounds in the category ''copper and copper compounds'') (Ref. 22). This approach is proposed because it is similar to the methodology used by TRI (Ref. 23). Although the type of threshold prompting the need to report would be similar to that for reporting in categories under TRI, it is important to note that reporting under CDR is for amounts manufactured (and imported), while reporting under TRI is for amounts released. It is also important to recognize that this method is different than reporting under CDR using a TSCA-listed chemical substance identity.

EPA is interested in obtaining comment on the proposal to allow reporting of inorganic substances in metal compound categories, including the methodology for how to report using categories. Specifically, EPA is interested in receiving comments on deviating from the standard approach used for CDR of reporting the volume of substance manufactured and instead using the approach of reporting the weight of the metal in the compounds when reporting by the metal category. Would it be more appropriate to report the full weight of the chemical substance instead of the metal weight? Are submitters likely to report using this approach?

Exclusions from category reporting. EPA is also proposing to require various substances to be reported as listed on the TSCA Inventory and not as part of these metal compound categories. Such substances are of particular interest to EPA, and would include:

- Substances that have been individually identified on the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 20): specifically, *Carbonic acid, barium salt (1:1)* (CASRN 513–77–9) (referred to as Barium carbonate);
- Substances that are the subject of certain TSCA actions as listed in 40 CFR 711.6, including TSCA section 5(a)(2) Significant New Use Rules (SNURs), TSCA section 5(b)(4) rules, TSCA sections 4, 5(e) and 5(f) orders, TSCA section 6 rules, TSCA section 4 test rules, Enforceable Consent Agreements (ECAs) developed under the procedures of 40 CFR part 790, and TSCA section 5 or 7 civil actions. Note that lists of subject chemicals can be identified using the eCDRweb reporting tool or separately from EPA's Substance Registry Services (SRS) website (*https://www.epa.gov/srs*). Instructions for determining subject chemicals are provided on the CDR website and in CDR guidance.
- Chemical substances undergoing prioritization or risk evaluation under TSCA section 6. While the current list

of chemical substances undergoing risk evaluation is comprised of ten chemicals that are not inorganic metal-containing compounds (Ref. 24), EPA may initiate risk evaluations for inorganic metal-containing chemicals in the future, which would exclude those chemical substances from being able to be reported to CDR under a metal compound category.

For example, consider reporting within the chromium category. There is a TSCA section 6 action (40 CFR 749.68) that covers several hexavalent chromium-based water treatment chemicals. Those covered substances (*e.g.,* Chromic acid (H2Cr2O7), sodium salt (1:2) (CASRN 10588–01–9), Chromic acid (H2CrO4) (CASRN 7738–94–5), and Chromium trioxide (CrO3) (CASRN 1333–82–0)) would not be reportable within the chromium category, even if they were manufactured as byproducts. However, other chromium substances, containing Chromium not in the hexavalent oxidation state (*e.g.,* Chromium chloride (CrCl3) (CASRN 10025–73–7), Chromium hydroxide (Cr(OH)3) (CASRN 1308–14–1), and Chromium oxide (Cr2O3) (CASRN 1308–38–9)), if manufactured as byproduct substances, would be able to be reported within the Chromium compound category.

2. *Specific site-limited recycled byproducts.* EPA is proposing to exempt specifically identified byproducts that are recycled on-site from two industries. Portland cement manufacturers that produce *Flue dust, portland cement* (CASRN 68475–76–3) (referred to as cement kiln dust), and manufacturers using the Kraft pulping process to produce *Sulfite liquors and Cooking liquors, spent* (CASRN 66071–92–9) (often comprised of what is referred to as black liquor) and *Carbonic acid calcium salt (1:1)* (CASRN 471–34–1) (referred to as calcium carbonate) would, under certain scenarios, be exempted from the need to report these byproduct substances. These byproducts would be exempted from reporting only when (1) they are recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured and (2) when the site is reporting under CDR the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.

Based on information provided by these two industries, these byproduct substances are directly recycled in physically enclosed systems in a site-limited manner (see definition of ''Site-limited'' at 40 CFR 711.3). For the purposes of CDR, EPA considers an enclosed system to be a system of equipment directly connected to the production process that is designed, constructed, and operated in a manner which prevents emissions, or the release of any chemical substance into the facility or environment during the production process. Such emissions, including fugitive emissions, could lead to exposures to workers, the public, or the environment. For an enclosed system, exposure and release could only occur due to loss of integrity or failure of the manufacturing process equipment or control systems.

To meet the EPA enclosed system scenario, any equipment that the byproduct is present in at any point during the process sequence, such as tanks, reaction vessels, reactors, processing units (*e.g.,* a drum filter), and/or connecting lines, must: (1) Be of high structural integrity and contained on all sides, (2) pose no foreseeable potential for escape of constituents to the facility or environment during normal use, and (3) be connected directly by pipeline or similarly enclosed device to a production process. Also, any transfers or holding steps occurring in this system must be necessary to the recycle process and must take place within physically enclosed equipment that meet the aforementioned criteria. For example, hard piping or completely sealed (*i.e.,* welded) equipment would meet these criteria if connected directly to other enclosed equipment, preventing potential releases including fugitive emissions.

EPA recognizes that there may be some potential for exposures and releases (*e.g.,* through non-routine cleaning of equipment, or maintenance operations) associated with such enclosed, site-limited systems, but believes the potential exposures and releases related to such systems are less than the potential exposures and releases associated with recycling systems that are not enclosed. Likewise, systems that transfer the byproduct to a different site for recycling or other use are expected to have higher levels of potential exposures and releases. For example, on-site recycling systems that rely on open troughs for moving material have an increased opportunity for exposures due to dusting or splashing as compared to the use of an enclosed pipe for moving material from one part of the manufacturing process to another.

Based on 2016 CDR data, the sites reporting under CDR within these two industries have reported chemicals that are related to these byproducts because they are subsequently manufactured from the byproducts or from other substances via the same overall manufacturing process. EPA therefore would collect exposure-related information about the manufacturing site for these two industries.

This proposed exemption is only for the volumes of the byproduct substance, listed at 40 CFR 711.10(c)(2)(i) (as proposed), that are recycled in a site-limited manner in physically enclosed systems of the same overall manufacturing process. Volumes that are used for a commercial purpose distinct from their manufacture as a byproduct remain reportable. Also, volumes that are removed from the enclosed systems, such as those that are stored in an open tank or pit, or stored in any non-connected tank or vessel, are excluded from this exemption and remain reportable.

Portland cement industry—Cement kiln dust. The Portland Cement Association (PCA) suggested that EPA should eliminate reporting requirements for cement kiln dust (CKD) that is temporarily stored before reintroduction into the Portland cement manufacturing process (Refs. 25 and 26). PCA suggested that their manufacture and recycling of cement kiln dust is similar to non-isolated intermediates, which are currently exempted from the need to report under CDR by 40 CFR 711.10(c)(4)(viii). However, EPA's existing policy with respect to non-isolated intermediates excludes storage in tanks or other vessels (*e.g.,* shipping containers) even if the vessels are part of an enclosed system.

There are circumstances where the cement kiln dust is stored for a period of time in a tank that is connected in an enclosed system with the other operating equipment. Because the cement kiln dust is stored, it cannot meet the requirements of the non-isolated intermediate exemption and therefore would need to be considered for reporting under CDR (Refs. 25 and 26).

EPA agrees that, based on the information provided by PCA, relevant portions of CKD processing meet the definition of enclosed as described for this proposed exemption; however it does not meet the non-isolated intermediate exemption. In addition, the recycling operation uses the CKD to manufacture clinker (which consists of Portland cement), which is reported under CDR by its component substances and therefore would supply the Agency with exposure information from a similar production process. Based on

CDR data submitted for the most recent principal reporting year (2015), EPA estimates that approximately 23 million lbs of CKD might meet the criteria established in this exemption. This is the amount of CKD that was reported as recycled and used on-site (out of the approximately 1.1 billion lbs total manufactured domestically in 2015).

Kraft pulping cycle—black liquor and calcium carbonate. The American Forest & Paper Association (AF&PA) provided EPA with extensive information about the Kraft pulping cycle and chemicals manufactured as part of that cycle. Most recently, AF&PA and other industry representatives communicated with EPA by petitioning for full exemption from CDR for four manufactured Kraft pulping cycle chemicals, by submitting comments in response to **Federal Register** notices related to the negotiated rulemaking, and by meeting with EPA to view and discuss a video providing an in-depth explanation of the Kraft pulping cycle (Refs. 27, 28, 29, and 30).

AF&PA identified that the Kraft pulping cycle begins with the production of black liquor as a byproduct of pulping in the production of paper, and the black liquor is subsequently used to manufacture green liquor. Calcium oxide and green liquor are used to manufacture white liquor, which results in the production of calcium carbonate as a byproduct. The calcium carbonate is recycled to produce calcium oxide. From the information provided, EPA believes that both black liquor and calcium carbonate are byproducts that are recycled in site-limited, enclosed systems. Based on CDR data submitted for the most recent principal reporting year (2015), EPA estimates that approximately 382 billion lbs of black liquor and calcium carbonate together might meet the criteria established in this exemption. This is the amount of black liquor and calcium carbonate that was reported as recycled and used on-site (out of the approximately 386 billion lbs total manufactured domestically in 2015). The other substances in the cycle are intentionally manufactured substances and would therefore continue to be reportable under CDR. Because the sites would be reporting these other substances, their production of black liquor and calcium carbonate would meet the requirements for this proposed exemption.

Changes to the list of exempted processes and related byproduct substances. EPA is proposing a petition process for the public to request changes to the list of exempted manufacturing processes and related byproduct substances. The initial exempted substances were selected based on information provided directly to EPA as part of the negotiated rulemaking-related activities and through other communications with these industries, as described elsewhere in this unit. Because there may be other manufacturing processes and related byproduct substances that meet the criteria for this exemption (as identified at the beginning of this unit) or EPA's interest in these byproduct substances may change, EPA may amend the list of byproduct substances and processes that have been proposed as part of this exemption. The Agency may do this on its own initiative or in response to a request from the public, based on EPA's determination of whether the manufacturing process and related byproduct substance described meet the criteria explained in this unit.

Any person would be able to request that EPA amend the manufacturing process and related byproduct substance exempted list. EPA is proposing to model the procedure to request amendments after the one described in 40 CFR 711.6(b)(2)(iii) to amend the list of partially exempted chemical substances for which the processing and use information is of low current interest. The proposed procedure would require a written request that identifies the process and byproduct chemical substance in question, including a written rationale for the request that provides sufficient specific information, including cites and relevant documents, to demonstrate to EPA that the byproduct substance(s) and manufacturing process(es) in question either would or would not meet the criteria for this exemption.

EPA is proposing to consider the following factors when evaluating a request to amend the list of exempted manufacturing processes and related byproduct substances: (1) Whether the byproduct substance is recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured; (2) whether the site is reporting under CDR other chemical substances, in particular a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process; (3) whether EPA has a current interest in the byproduct substance; and (4) whether the byproduct substance must have already been reported under CDR or would be expected to be reported if not exempted by this exemption.

Regarding the second consideration, EPA expects to be able to ascertain typical exposure scenarios for the process based on information for other substances that are reported at the facility in the same or similar manufacturing process. If no other substances are reported, EPA would not have any exposure-related information about the manufacturing site.

Regarding the third consideration, EPA may have a current interest in a byproduct substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an ECA developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA sections 4, 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7. As noted earlier, lists of subject chemicals can be identified using the eCDRweb reporting tool or separately in EPA's Substance Registry Services (SRS). Instructions for determining subject chemicals are provided on the CDR website and in CDR guidance. EPA may also have a current interest in a byproduct substance that is undergoing risk evaluation, is being considered for prioritization, or that has particular uses or attributes that are of interest. This list is not exhaustive. For example, EPA may have a current interest for other reasons, including activities under other statutes, such as the Resource Conservation and Recovery Act (RCRA).

If a request related to a particular byproduct substance and process is resubmitted, any subsequent request would need to clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request. EPA would issue a written response to each request within 120 days of receipt of the request. As needed, the Agency would initiate rulemaking to revise the list of exempted byproduct substances. To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, requests would be required to be submitted to EPA no later than 12 months prior to the start of the next principal reporting year. EPA is interested in comments that may improve the proposed process for requesting amendments to the manufacturing process and related byproduct substance exempted list.

3. *Byproducts generated by specified non-integral processes.* EPA is also proposing to exempt byproducts manufactured in certain equipment via processes that are not integral to the production process. An integral process

is the portion of the manufacturing process that is chemically necessary or provides primary operational support for the production of the intended product. For the purposes of this exemption, certain associated processes that are not chemically required to produce the intended product would be considered non-integral. These may be required due, for example, to other regulations or the need to generate heat or electricity on-site, but not specifically necessary for the manufacture of the intended product. In this proposal, byproducts manufactured due to the use of pollution control equipment and boilers that generate heat or electricity on-site, when such equipment is not part of the main production process, would be exempted from reporting under CDR.

The site must continue to report chemical substances that are subsequently manufactured from these byproducts. The production of byproducts in equipment that is integral to the production processes remain subject to reporting as well, unless otherwise exempted. For example, utilities that produce electricity as a product may be using boilers as part of their production of electricity, and therefore those boilers are considered equipment integral to the production process. Thus, byproducts produced by these electric utility boilers would continue to be subject to reporting. Another example, reverberatory furnaces, which may function similarly to some boilers, can have a chemical processing function such as smelting. This and similar equipment, when used in such scenarios, would be considered integral to the main production process and any resultant manufactured byproduct substances would continue to be subject to reporting.

Examples of non-integral pollution control equipment include flue gas desulfurization and selective catalytic reduction systems. Under this proposed exemption, if a byproduct substance produced from this equipment is recycled for a non-exempted commercial purpose, the byproduct would be exempted from reporting under CDR. However, any chemical substance manufactured from the otherwise exempted byproduct would be subject to reporting unless otherwise exempted or the manufactured volumes are below the reporting threshold. EPA is interested in receiving comments on other examples of non-integral pollution control equipment, including descriptions of potential byproducts that could be produced in such equipment.

In reviewing how the CDR information is used, EPA believes the information about byproducts produced from the identified non-integral equipment is generally less critical to be obtained via CDR than information about byproducts produced from integral equipment for risk evaluations conducted under TSCA. Release from pollution control equipment can often be obtained through national inventories such as TRI. Among other tools, EPA uses generic scenarios, including OECD-approved Emission Scenario Documents, to develop environmental release assessments. The generic scenarios can be used in combination with information from CDR to develop estimates of facility releases. These Emission Scenario Documents do not include emissions from non-integral equipment; thus, CDR data from such equipment are generally not needed to support these environmental release assessments. EPA is interested in comments that may improve the approach proposed for this exemption.

E. General Regulatory Text Updates

EPA is also proposing to make other general updates to the regulatory text in 40 CFR part 711 that have been identified subsequent to the CDR rule's original promulgation in 2011. The general updates to the regulatory text include removing outdated text, consolidating byproduct-related exemption text, and simplifying and clarifying language throughout the regulatory text.

1. *Removing outdated regulatory text.* EPA is proposing to remove regulatory text specific to the 2012 CDR submission period. This text is no longer relevant because the submission period was completed more than five years ago and all phased-in reporting requirements from the change from the IUR to CDR have been fully in effect since the 2016 reporting cycle.

2. *Consolidating byproduct exemption regulatory text.* EPA is proposing to consolidate regulations regarding byproduct exemptions that affect reporting under the CDR rule into 40 CFR 711.10, such that all the CDR reporting exemptions regarding manufacturer activities are in one place. EPA expects such consolidation would make it easier for manufacturers to determine whether all or only some of their manufacturing activities are required to be reported under CDR, or whether all or some of their manufacturing activities are exempted from the need to be reported. Specifically, EPA is proposing that new exemptions proposed in this notice and language from 40 CFR 720.30(g) and (h) that is currently incorporated by reference would be replicated in 40 CFR 711.10(c). EPA intends to continue to interpret the replicated language in the same way as it has been interpreted under CDR, which for the most part aligns with how it has been interpreted under the TSCA section 5 Pre-Manufacture Notice (PMN) program. However, there are differences between the two programs that may result in different applications of the exemptions covered by this replicated regulatory text, and listing all exemptions in the CDR regulations instead of cross-referencing to the PMN regulations would allow for flexibility in the future as EPA continues to further analyze the CDR reporting exemptions.

3. *Simplifying and clarifying regulatory text.* EPA is proposing to change or add regulatory text to simplify or clarify regulatory requirements throughout 40 CFR part 711. These proposed changes are in addition to changes necessary for proposals discussed elsewhere in this notice, and include revisions to:

- 40 CFR 711.1(a) to remove the discussion about compiling and keeping current the TSCA Inventory, including the discussion about adding new chemicals to the Inventory. This discussion is unnecessary for an understanding of the scope of the CDR rule.
- 40 CFR 711.1(c) to include a statement about TSCA section 11 subpoena authority, as a reminder that EPA has this authority for compliance purposes.
- 40 CFR 711.3 definitions for *e-CDRweb, Manufacture,* and *Site* for clarification purposes.
- 40 CFR 711.6(a)(4) to reverse the order of ''certain forms of natural gas'' and ''water'' for clarification purposes.
- 40 CFR 711.10 to remove duplicative wording and add clarity to the requirements.
- 40 CFR 711.15(a) to add clarity to the reporting requirements.
- 40 CFR 711.35(c)(1) to update references.

IV. Detailed Discussion of the Proposed Modifications to Small Manufacturer Definition and Size Standards

EPA is proposing modifications to the TSCA section 8(a) small manufacturer size standards, as required, following EPA's determination on November 30, 2017 that revision to the current size standards is warranted (82 FR 56824). The proposed standards would apply to small manufacturers for TSCA section 8(a) rules, including CDR, unless a different standard is identified in the regulatory text of a particular rule. EPA

is also proposing a TSCA section 8(a) definition for small government entities.

Initially, when TSCA was implemented in the 1970's, EPA took a case-by-case approach to the definition of small manufacturers and processors and established individual size standards for each TSCA section 8(a) rule. EPA then developed a general 8(a) small manufacturer definition and size standards. These standards, finalized in the **Federal Register** of November 16, 1984 (49 FR 45425), have not been changed, although variations have been used for selected chemical-specific rules. See Unit II.C. of this action for additional information, including a description of the current standard.

A. Scope and Content of the Proposed Small Manufacturer Definition Update

For the TSCA section 8(a) small manufacturer definition update, EPA is proposing to update the current definition based on inflation. EPA is interested in public consideration of this approach and is soliciting comments regarding the extent to which this approach would reduce the reporting burden for those small manufacturers with fewer available resources, while ensuring Agency information needs are still met.

The proposed modification to the TSCA section 8(a) small manufacturer size standards are based on a number of factors, including: (1) Information gathered during meetings with the Small Business Administration, including the Office of Advocacy, regarding its definition of small business (Ref. 31); (2) preliminary comments and suggestions from representatives of the chemical industry, nongovernmental organizations, and state, local, and tribal governments submitted when EPA published its final determination that a revision to the standards is warranted (82 FR 56824, November 30, 2017); (3) review of various alternative exemption criteria; and (4) comments received on EPA's User Fees for the Administration of the Toxic Substances Control Act proposed rule (TSCA Fees Rule) (83 FR 8212, February 26, 2018). Documentation of these meetings, comments, and the analysis can be found in the dockets for the determination (EPA–HQ–OPPT–2016–0675), the proposed TSCA Fees Rule (EPA–HQ–OPPT–2016–0401), and this proposal (EPA–HQ–OPPT–2018–0321).

The proposed definition would be applicable to chemical manufacturers (including importers), but not to chemical processors. Because the scope of EPA's analysis of the proposed definition is focused on impacts to the CDR, in which reporting is required by manufacturers and not processors, EPA believes it is best to continue the past practice to develop definitions, as applicable, for small processors on a rule-by-rule basis. In addition, EPA has reviewed the existing TSCA section 8(a) rules that contain definitions for small processors. Because EPA has not received any reports under those rules for at least ten years, EPA believes that applying this proposed definition to processors would have no impact (Ref. 32). EPA welcomes comment on whether the proposed definition should be expanded to include processors.

All data in this preamble represent impacts to the manufacturing portion of the chemical industry, as evaluated for the CDR. The proposed definition is as follows:

Proposed small manufacturer definition: EPA is proposing to base the update of the current two-standard definition at 40 CFR 704.3 on inflation by adjusting the sales standard level for the first part from $40 million to $110 million and for the second part from $4 million to $11 million. Under this proposal, EPA would use the same definition for all manufacturers, except for small governments as discussed in this unit. The impacts of this option are provided in Unit I.E.2. The definition under this proposal would read:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Under CDR, sites that meet the small manufacturer requirements are exempted from the need to report either for the full site (based on the second standard) or for particular chemical substances (based on the first standard), unless the chemical substance the site is manufacturing (including importing) is the subject of one of certain TSCA actions: A rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, or is the subject of an order in effect under TSCA section 5(e), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7. As part of this proposal, EPA is proposing to add TSCA section 4 orders to the list of certain TSCA actions. The authority to issue section 4 orders was added to TSCA when the statute was amended in 2016.

The current small manufacturer definition at 40 CFR 704.3 includes an inflation index to provide direction for determining the need to update the two standards comprising the definition (see Unit II.C.). For future inflation adjustments, EPA is proposing to use the Gross Domestic Product (GDP) deflator, or implicit price deflator, instead of the Produce Price Index (PPI) for Chemical and Allied Products when determining the need to adjust the total annual sales values. EPA is making this proposal because the types of small manufacturers subject to TSCA section 8(a) reporting requirements are broader than those defined by the PPI for Chemicals and Allied Products, which covers only Chemicals and Allied Products. The GDP deflator is less volatile and is broader than the PPI for Chemicals and Allied Products, and therefore EPA believes it is a better measure for considering an update to the revenue size standards in the proposed definition.

EPA estimates that the proposed definition would eliminate reporting entirely for 93 industry sites and would reduce reporting by eliminating the need to report at least one chemical for an additional 129 industry sites (Ref. 5). Overall, 888 chemical reports from industry sites would no longer be submitted to CDR. In sum, the use of the inflation adjustment definition results in a reduction of 2 percent of sites, an overall reduction of 2 percent of chemical reports, and a reduction of 0.07 percent of total volume reported (Ref. 5).

Proposed small governments definition. In addition to the proposed update to the definition for small manufacturers, EPA is proposing a definition for small governments. Currently, there is no small government definition in TSCA section 8(a). During the 2016 CDR reporting period, EPA became aware that the governments were reporting under CDR. Examples of governments considered to be manufacturers include a publicly owned water treatment facility that manufactures ozone onsite for water treatment, or a municipal landfill that

captures methane gas to be sold. EPA is proposing a small government definition to reduce the reporting burden for governments that may lack necessary resources. EPA proposes to use the same definition for small governments as the Regulatory Flexibility Act (5 U.S.C. 601(5)): A small governmental jurisdiction is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. States and tribal governments are not considered small governments. EPA is interested in comment on whether this definition should be changed for TSCA section 8(a) purposes to also include Tribal governments.

EPA estimates 33 government sites report under CDR in a four-year cycle. Under the proposed definition of small governments, reporting would be eliminated entirely for four government sites with an associated six chemical reports.

Application of standards. The size standards in this proposed rule would apply to all manufacturers of chemical substances subject to TSCA section 8(a) reporting and recordkeeping rules, unless the Agency specifically provides otherwise in a particular TSCA section 8(a) rule. Rules with different definitions than the current small manufacturer definition at 40 CFR 704.3 are: the nanoscale rule at 40 CFR 704.20; certain chemical-specific rules at 40 CFR 704.43 (Chlorinated Naphthalenes) and 40 CFR 704.102 (Hexachloronorbornadiene); and the Preliminary Assessment Information Rule (PAIR) at 40 CFR 712. Because of an inadvertent error there is currently no applicable definition of ''small manufacturer'' in 40 CFR 704.104 (Hexafluoropropylene oxide); EPA is proposing a correction, as discussed later in this unit.

Nanoscale materials. On January 12, 2017, EPA finalized the TSCA section 8(a) reporting and recordkeeping rule for nanoscale materials, which specified a separate small manufacturer definition (82 FR 3641). The nanoscale materials rule at 40 CFR 704.20 specifies the following definition: Small manufacturer or processor means any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million. In November 2017, when EPA determined that the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 warranted revision, EPA did not make a determination as to whether the definition in the nanoscale materials rule warranted revision. After further evaluation and consideration, EPA has determined that the size standard in the nanoscale materials rule definition does not warrant revision.

In the process of making this determination, EPA evaluated the effect of adjusting the small manufacturer size standard for nanoscale materials for inflation and found that it would cause no measurable impact on the number of reports received. Furthermore, since the first reports for nanoscale materials, which would make up a large portion of reported information, are due within one year after the final effective date of the rule and before any newly proposed small manufacturer definition would take effect, EPA does not want to complicate the process or potentially confuse regulated entities who are in the process of compiling the required information.

Certain chemical-specific TSCA section 8(a) rules. In addition to the nanoscale rule, there are eight chemical-specific rules listed in 40 CFR 704 subpart B. Five of those rules refer to the current TSCA section 8(a) small manufacturer definition listed in 40 CFR 704.3 and therefore would be impacted by the proposed approach for updating the standards. These impacted five rules are: §§ 704.25 (11-Aminoundecanoic acid); 704.33 (P-tert-butylbenzoic acid (P–TBBA), p-tert-butyltoluene (P–TBT) and p-tert-butylbenzaldehyde (P–TBB)); 704.45 (Chlorinated terphenyl); 704.95 (Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis-(EDTMPA) and its salts); and 704.175 (4,4′-methylenebis(2-chloroaniline) (MBOCA)). One of the chemical-specific rules in 40 CFR 704 subpart B, 40 CFR 704.104 (Hexafluoropropylene oxide), only includes a rule-specific small processor definition and not a small manufacturer definition. Upon review, EPA finds this to be an inadvertent error. As originally promulgated, 40 CFR 704.104 included the small manufacturer standard via the cross reference in 40 CFR 704.104(c)(2) to the exemption provisions in 40 CFR 704.5 which was lost when the exemptions at 40 CFR 704.5 were amended and the necessary corresponding change was not made at 40 CFR 704.104(c)(2) (52 FR 41297, October 27, 1987 and 53 FR 51717, Dec. 22, 1988). As such, EPA is including in this proposal a technical correction to address this error.

Two of the chemical-specific rules, namely 40 CFR 704.43 (Chlorinated Napthalenes) and 40 CFR 704.102 (Hexachloronorbornadiene) have their own rule-specific small manufacturer definitions. EPA is not proposing to change the definitions for these two rules because it has been over ten years since EPA has received any reports under these rules. EPA therefore believes a change to the small manufacturer definitions for these rules would have no impact. However, EPA is interested in comment on whether the small manufacturer definitions for these two rules should be changed.

PAIR rule. EPA is proposing to update the current small manufacturer definition in the PAIR rule at 40 CFR 712.25. EPA promulgated the TSCA section 8(a) PAIR rule in June 1982, to collect information to identify, assess and manage human health and environmental risks from chemical substances, mixtures, and categories listed on the rule. The 1982 PAIR small manufacturer definition predates the current 40 CFR 704.3 small manufacturer definition and has not been updated. It states: A manufacturer is qualified as small if both of the following criteria are met: (1) Total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period; [and] (2) Total production of the listed substance for the reporting period was below 45,400 kilograms (100,000 pounds) at the plant site. EPA is proposing to use the small manufacturer definition in 704.3 for the PAIR rule.

B. Agency Objectives

Industry compliance with TSCA reporting and recordkeeping requirements involves the expenditure of time, money, and personnel resources. These costs have particular impact on companies that have limited financial and personnel resources, such as smaller firms. Such manufacturers tend to have fewer administrative personnel and less capability for data compilation and recordkeeping than larger firms.

However, while recognizing the burdens on smaller firms, EPA is required to make risk management decisions based on reasonably available information, such as that collected through CDR. The information collection authority of TSCA section 8(a) reflects congressional recognition of EPA's need for sufficient data from the chemical industry. EPA has concluded that if a firm produces a subject chemical in substantial quantities, it is inappropriate to exempt that company from TSCA section 8(a) reporting requirements. Production data is valuable to EPA as an indicator of chemical exposure and high volume chemical production reflects a greater potential for environmental release. For this reason, EPA is maintaining the annual production or importation

volume modifier of 100,000 pounds for the first part of the proposed updated small manufacturer definition.

EPA also has the authority to develop new size standards separate from the general 8(a) small manufacturer definition in this proposed rule. Such development would be done in appropriate cases when the Agency finds that the general TSCA section 8(a) small manufacturer definition is not suitable for a new specific TSCA section 8(a) rule. However, when changing the definition for a specific rule, EPA must follow full notice and comment rulemaking procedures with regard to the amended definition and size standards.

EPA has an additional objective for the general TSCA section 8(a) small manufacturer definition and size standards. The standards should not prevent TSCA section 8(a) rules from providing information that is representative of firms of different sizes. Large and small firms have varying amounts of capital available, and therefore may utilize different production processes, techniques, and equipment. Different methods of production may cause the potential for chemical exposure to vary among large and small firms. It is important for the Agency to be able to monitor these differences. To ensure that EPA would receive information from a representative portion of manufacturers regulated under TSCA section 8(a), the structure of the definitions and levels of the size standards have been designed to allow the Agency to obtain production, use, and exposure data from a variety of firms.

A final objective for the standards is that they be easily analyzed and applied by both industry and the Agency. EPA is proposing exemption criteria that represent readily available data. These data enable identification of companies which would be likely to qualify for a small manufacturer exemption. The standards could also be easily enforced because the selected criteria would enable EPA to monitor compliance with the exemption.

C. Agency Approach and Methodology

In developing the size standards proposed in this rule, EPA examined the utility of several possible criteria for ''small'' as possible measures of chemical exposure potential and the resources available to manufacturers.

EPA looked at criteria for ''small'' used by other agencies, reviewed other ''small'' manufacturer definitions used by EPA, and reexamined criteria used for past rules under TSCA section 8(a), with specific focus on the recently finalized TSCA section 8(a) nanoscale materials rule (82 FR 3641, January 12, 2017). EPA considered the possible utility of parameters that have not been used previously, such as market share and net profit. EPA also relied on the input of industry representatives documented in the docket for the final determination that a revision to the standards is warranted and from SBA in meetings with EPA staff (82 FR 56824/EPA–HQ–OPPT–2016–0675–0022 and Ref. 31).

No parameter or set of parameters can meet EPA objectives and requirements perfectly. The various types of parameters considered, and their possible levels, are only approximations of company resources or EPA's information needs. EPA reviewed industry comments from the determination, as well as considerations factored into the development and evaluation of the original definitions, in selecting standards which best meet the Agency's requirements. EPA also took into consideration the comments on the TSCA Fees Rule (83 FR 8212, February 26, 2018), regarding the definition of small manufacturer. The following unit describes EPA's evaluation of possible alternative definitions.

D. Evaluation of Alternative Criteria for Small Manufacturer Definitions and Analysis of Selected Options

In the definitions used in the past by other Federal agencies, as well as at EPA under TSCA, there is no single definition of a ''small'' business. The definitions and size standards differ according to context and purpose. Identified broad categories include (1) benefits distribution, (2) data analysis and reporting, and (3) regulation and information collection (where flexibility is sought in balance with program objectives) (Ref. 5).

When establishing its size standards, SBA examines various industry characteristics such as average firm size, degree of competition within an industry, start-up costs and entry barriers, and distribution of firms by size. SBA also evaluates federal market factors including a small business's share in total industry's receipts. For more details, please see the ''SBA's Standards Methodology'' white paper, available at *www.sba.gov/size.* The SBA size standards are industry-specific mostly based on either average annual revenue or number of employees, for reference please see the SBA size standards at 13 CFR 121.202. In order for an entity to be classified as a small business for federal contracting and other small business programs, its enterprise level revenue or number of employees (including all affiliates) shall not exceed the size standard for the applicable industry. These size thresholds are determined at the 6-digit North American Industry Classification System (NAICS) levels. SBA's employee-based size thresholds range from 100 to 1,500 employees to account for differences among NAICS codes.

The size standards are intended to reflect the degree of competition within individual industries. SBA size standards vary by industry type to reflect the unique competitive characteristics of different industries. In some cases, SBA uses a revenue standard, or defines a business size in terms of assets. In other cases, the size standard is based on the number of employees. Within the chemical industry, the values assigned to the employment standards vary considerably among different industry groupings, which are represented using NAICS codes (Ref. 5).

For purposes of data analysis and reporting, Bureau of the Census (Census) uses a size standard of employee number at 500 to separate small businesses into their own subgroup for data reporting. Similarly, the U.S. Department of Agriculture's (USDA) Economic Research Service (ERS) identifies small farms at less than $350,000 farm income for reporting and research purposes. The purpose of these small business definitions is to identify companies whose paperwork burden can be lessened without substantial impact on the agencies' information bases (Ref. 5). Similarly, but to a much greater extent, small business definitions developed in regulatory contexts involve detailed program-specific balancing considerations. For example, the Occupational Safety and Health Administration (OSHA) defines a small business as having 10 employees or fewer for their Fire Protection in Shipyards regulations (Ref. 5).

Not unlike other federal agencies with similar purposes, EPA has separate definitions for ''small'' manufacturers, producers, processors, waste generators, and facilities under different statutes or regulations, including the National Primary Drinking Water Regulations, National Pollutant Discharge Elimination System Permit Regulations, RCRA laws, and the TRI. Each definition was created to meet individual programmatic needs or statutory requirements; it is therefore difficult to draw comparisons across the different definitions. For more information on the different ''small'' entity definitions used by other federal agencies and EPA, see Tables B–2 and B–3 in the Economic Analysis (Ref. 5).

When EPA first established the general TSCA section 8(a) small manufacturer definition at 40 CFR 704.3 (49 FR 45425, November 16, 1984), EPA considered a number of possible parameters for the size standards, including: (1) Total annual company profit, (2) total company assets, (3) total annual company sales, (4) annual chemical sales, (5) number of company employees, (6) annual production volume per chemical, and (7) market share. When EPA reevaluated the size standards (82 FR 56824, November 30, 2017), the Agency considered the initial parameters again and additionally considered (8) barriers to entry, (9) start-up or expansion costs, (10) average firm size as a factor of employment and sales, (11) industry competition and concentration, (12) growth trends, and (13) technological changes, which were suggested by SBA's Office of Advocacy during the comment period and SBA consultation as part of EPA's determination process for reviewing whether revision to the current size standards for small manufacturers and processors was warranted (82 FR 56824, November 30, 2017).

To consider these parameters for this proposed rule, EPA explored SBA's approach to defining small businesses: A manufacturer (including importer) is defined as small in accordance with the size standards identified by NAICS codes at 13 CFR 121.201. EPA considered adopting an SBA-based size-standard in combination with various production volume modifiers such as 25,000; 50,000; and 100,000 pounds. For example, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 50,000 pounds, the manufacturer (including importer) would not qualify as small for purposes of reporting on the production or importation of that substance at that site.

EPA examined the impact of the various SBA-related definitions and the inflation adjusted definition on the number of reports, including by subcategories of particular interest to EPA such as TSCA Work Plan chemicals and by overall production volume. Details are in Table 2–1 of the Economic Analysis (Ref. 5). Any of the revised small manufacturing definitions considered resulted in fewer retained reports. Some of the definitions resulted in the addition of reports that are currently exempted. Details are in Tables 5–15 and 5–16 of the Economic Analysis (Ref. 5).

Comparing the options by the amount of overall production volume reported provides another insight into the impacts. Under the SBA-based size standards with production volume modifiers of 50,000 and 100,000 pounds, 38 million and 96 million pounds would be exempted, respectively. In comparison, under the inflation adjusted option, 13.7 billion pounds would be exempted. When compared to the baseline production volume, these would result in the retention of reporting on 99.93 percent (inflation adjusted), 99.9998 percent (SBA-based size-standard with a production-volume modifier of 50,000 pounds) and 99.9995 percent (SBA-based size-standard with a production-volume modifier of 100,000 pounds). In addition, under the inflation adjusted option the average report exempted 15.5 million pounds, whereas under the SBA-based size standards with production volume modifiers of 50,000 and 100,000 pounds, the average report exempted 23,000 pounds and 37,000 pounds, respectively. More details are in Tables 5–15 and 5–16 of the Economic Analysis (Ref. 5).

After analyses, the agency determined that adopting SBA's definition with the various production volume modifiers would likely result in loss of information for TSCA implementation, such as information on TSCA Work Plan chemicals. Given the impacts on losses to the CDR information necessary for the TSCA program coupled with the inherently higher complexity of an SBA-based definition (system involving a mix of revenue and employment bases with levels of size standards varying according to NAICS), EPA chose to propose the inflation adjustment option. EPA is, however, interested in comments on adopting the SBA standard (or an SBA-like standard) for small manufacturers, with an alternative production volume modifier, instead of the proposed definition. Details of SBA's standard can be found at 13 CFR 121.201 and on their website (Ref. 33). Details of EPA's analysis, options considered, and conclusions are summarized in detail in the Economic Analysis (Ref. 5).

Proposed definition: EPA adjusted the current size standards at 40 CFR 704.3 to account for inflation, resulting in an increase of the total annual sales from $40 million to $110 million for the first standard while maintaining the requirement that annual production or importation volume not exceed 100,000 pounds, and resulting in an increase of the total annual sales from $4 million to $11 million for the second standard. This proposed definition would reduce the amount of information reported under CDR, resulting in a decrease of 2 percent of chemical reports submitted, 2 percent of sites reporting, and 1.4 percent of total chemicals reported from the baseline conditions of the current definition. The baseline conditions are described in the Economic Analysis (Ref. 5). In future cycles, this proposed definition would reduce overall reporting burden by an estimated −64,295 hours and result in a $4,988,270 cost savings over a four-year CDR reporting cycle (Ref. 5). See also Unit I.E.2.

EPA's full analysis of the costs, cost savings, and benefits of this proposed definition is presented in detail in the Economic Analysis (Ref. 5). EPA welcomes comments on this proposal and on the other options and size standards EPA considered for evaluating the revised definition. In particular, EPA is seeking comments on an alternative definition for a small manufacturer (*e.g.,* an employment-based size standard varied by industry or a combination of employment-based and revenue-based varied by industry, such as the SBA standard with a 50,000 pound production volume modifier described previously in this unit of the preamble) which meets EPA's goal to minimize loss of chemicals and site reporting while maximizing reporting burden reductions for small businesses. A description on the SBA definition and a listing of other Federal government definitions for small business, including the employment-based definition used for the final TSCA Fees Rule (83 FR 52694, October 17, 2018), is provided in Appendix B of the Economic Analysis (Ref. 5).

V. Request for Comment

EPA requests comment on all changes and other topics described in this proposed rule, and the Economic Analyses prepared in support of this proposed rule (Refs. 4 and 5). EPA encourages all interested persons to submit comments on the issues identified in this Notice and to identify any other relevant issues as well. This input will assist the Agency in developing final rules that successfully addresses information needs while minimizing potential reporting burdens associated with the rule. EPA requests that commenters making specific recommendations include supporting documentation where appropriate.

EPA is also interested in receiving comment on whether reporting production volumes in ranges instead of to two significant figures would reduce burden for submitters while continuing to provide the information needed by EPA for implementation of TSCA. The current requirement to report to two

significant figures is, in essence, the reporting of a midpoint of a range. For example, if reporting 120,000 pounds, the actual production volume would be between 115,000 and 124,999 pounds. If reporting in ranges would reduce burden, should the ranges apply to a subset of reporters (such as inorganic chemicals or byproduct chemical substances), for lower production volumes only, as is done in TRI, (such as under 25,000 pounds), or to all? EPA is also interested in how a reporter would determine the percentage production volume required for physical form and processing and use information when reporting the underlying production volume in ranges.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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2. EPA (2017). CDR Outreach meeting with Earthjustice and Other NGOs. Attended by Earthjustice, Safer Chemicals Healthy Families, Environmental Health Strategy Center, and EPA. Washington, DC. July 17, 2017.
3. EPA (2017). CDR Outreach meeting with Environmental Defense Fund (EDF). Attended by EDF and EPA. Washington, DC. July 19, 2017.
4. EPA (2018). *Economic Analysis for the Proposed Rule on TSCA Chemical Data Reporting (CDR) Revisions—(RIN 2070–AK33).* Office of Pollution, Prevention, and Toxics. Washington, DC. August 2018.
5. EPA (2018). *Economic Analysis for the Proposed Rule on TSCA Section 8(a) Small Manufacturer Definition Update (RIN 2070–AK33).* Office of Pollution, Prevention, and Toxics. Washington, DC. August 2018.
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18. EPA (2018). CDR—Co-Manufacturing and Other Reporting Mechanics; Internal meeting. Attended by representatives of American Chemistry Council (ACC) and EPA. Washington, DC. February 12, 2018.
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VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

The EPA prepared two economic analyses of the potential costs, cost savings, and benefits associated with this action. A copy of these economic analyses, entitled *Economic Analysis for the TSCA Chemical Data Reporting Revisions Rule* (Ref. 4) and *Economic Analysis for Proposed Rule on the TSCA Section 8(a) Small Manufacturer Definition Update* (Ref. 5), are available in the docket and is briefly summarized in Unit I.E.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

The CDR revisions and TSCA section 8(a) small manufacturer definition update are part of an action that is expected overall to be a deregulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017).

C. Paperwork Reduction Act (PRA)

For CDR, the information collection requirements in 40 CFR part 711 related to the submission of Form U's are already approved by OMB under the PRA, 44 U.S.C. 3501 *et seq.* That information collection request (ICR) has been assigned EPA ICR No. 1884.11 and OMB Control No. 2070–0162. Because this proposed rule involves new or revised information collection activities that require additional OMB approval, EPA has prepared an addendum to the currently approved ICR (Ref. 34 and 83 FR 36928, July 31, 2018 (EPA–HQ–OPPT–2017–0648). You can find a copy of the ICR addendum in the docket for this proposed rule (EPA–HQ–OPPT–2018–0321), and it is briefly summarized here.

The ICR addendum quantifies the burdens associated with the proposed CDR revisions and TSCA section 8(a) small manufacturer definition update (RIN 2070–AK33). EPA is proposing revisions to the CDR rule for three primary reasons: Align with amended TSCA, increase the usefulness of the CDR data collected, and reduce burden for CDR reporters pursuant to TSCA section 8(a)(5). The CDR data collection provides chemical manufacture, processing, and use information that helps EPA identify what chemicals the public may be exposed to as consumers or in commercial and industrial settings. The data also help EPA assess routes of potential exposure to those chemicals.

The PRA mandates that federal agencies estimate the recordkeeping and reporting burden of a rule. In this context, the term ''burden'' is interpreted as the total time, effort, or financial resources expended by individuals to generate, maintain, retain, disclose, or provide information to or for a federal agency. It includes the time regulated entities need to review instructions and to develop, acquire, install, and use technology and systems to collect, validate, verify, and disclose information. It also includes time taken to adjust existing ways to comply with any previously applicable instructions and requirements and to train personnel to respond to the information collection task.

For CDR, users submit data to EPA using a Form U on a four-year reporting cycle for the ''principal year'' and for the years since the previous principal reporting year (currently three years). Completion of the Form U involves reporting on a per-site basis for each of the reportable chemicals at that site. Therefore, each site subject to CDR requirements is considered a respondent that will submit one Form U (response) on one or more chemicals. Sites are subject to CDR reporting requirements when annual chemical production volume is at or above reporting thresholds (typically 25,000 lbs, but 2,500 lb for certain reporters) in any calendar year in the principal reporting year and the previous three years. There is one response per respondent, as one Form U per site accommodates multiple chemical reports in the same submission. Activities for preparing and submitting a CDR reporting form include rule familiarization, compliance determination, form completion, and recordkeeping.

The changes covered by the proposed CDR revisions fall in to the following categories:

- Co-manufacturer reporting;
- Modifications and additions to reportable data elements;
- Changes to claiming confidentiality; and
- Byproduct provisions.

The changes proposed for the TSCA section 8(a) small manufacturer definition update are as follows:

- *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any) are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 100,000 pounds, the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under the second standard of this definition.
- *Second Standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

These changes are described in further detail in the CDR ICR Addendum (Ref. 34). Table 2 summarizes the changes to reporting under this proposed definition.

TABLE 2—CDR ICR ADDENDUM SUMMARY—ANNUAL BURDEN AND COST

Respondents/affected entities:	Entities potentially affected by this ICR include companies manufacturing (including importing) chemical substances listed on the TSCA Inventory and regulated under TSCA section 8.
Respondent's obligation to respond:	Respondents are obligated to report to EPA.
Estimated number of respondents:	5,660.
Frequency of response:	The collection occurs every four years. The next CDR collection will occur in 2020.
Estimated annual incremental burden:	25,201 hours.
Estimated annual cost:	$1,955,042.

For TSCA section 8(a) reporting outside of CDR, including the TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) or any of the chemical specific TSCA section 8(a) rules, EPA does not estimate incremental burden and cost either because EPA has not received any chemical reports under the rule for an extended period of time, or because the rule uses a different definition that is not being changed by this proposal.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov,* Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than May 28, 2019. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I certify that this action will not have a significant adverse economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in two Economic Analyses (Refs. 4 and 5).

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as:

1. A small business, as defined by the SBA's regulations at 13 CFR 121.201;

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and not dominant in its field.

The regulated community does not include small not-for-profit organizations. Additionally, no small governments are expected to be adversely affected by the proposed rule; in fact, the proposal creates an exemption for small governments. Therefore, the focus of the RFA analysis is on small businesses.

The existing CDR rule, at 40 CFR 711.9, generally exempts from reporting small businesses, defined at 40 CFR 704.3 as entities with annual sales of less than $40 million and less than 100,000-pound production of any given chemical substance at a site; or annual sales of less than $4 million. Note that under the proposed rule, as under current regulations, a small business would be ineligible for the exemption if it produces any chemical substance that is the subject of a regulation proposed or promulgated under TSCA sections 4, 5(b)(4), or 6; that is the subject of an order in effect under TSCA sections 4 or 5(e); that is subject to a consent agreement under TSCA section 4; or that is the subject of relief that has been granted pursuant to a civil action under TSCA sections 5 or 7. A small business may also report voluntarily.

For purposes of the economic analysis covering the CDR revisions portion of the proposed rule (Ref. 4), this small manufacturer exemption is assumed to be unchanged. Conversely, for the TSCA section 8(a) small manufacturer definition update portion of the rule (Ref. 5), reporting requirements on the Form U are assumed to be unchanged with changes to the exemption as the focus of the Economic Analysis (Ref. 5). Further discussions in this unit summarize results from each economic analysis, and then provide the synthesized overall conclusion.

1. *CDR revisions.* EPA analyzed potential small business impacts from this proposed rule for purposes of the small entity analysis using the SBA size standards which are either revenue or employment based, depending on the industry sector. EPA estimates that 732 small parent entities would potentially be affected by the CDR revisions portion of the proposed rule. Based on estimated maximum compliance costs annualized over a 10-year period and average revenue data for parent entities, EPA estimates that the cost-to-sales ratio of the proposed rule would be less than one percent for 728 (99.45 percent) of small parent entities subject to the rule. An additional two small parent entities are expected to incur cost impacts between one and three percent, and two small parent entities are expected to incur cost impacts above three percent (Ref. 4). Per EPA guidance, even if impacts are greater than one percent, as long as the number of entities is fewer than 100 and less than 20 percent of total small entities, the proposed rule is determined to not result in a significant impact on a substantial number of small entities. Therefore, EPA concludes that compliance costs associated with CDR revisions portion of the proposed rule are not expected to have a significant economic impact on a substantial number of small entities (no SISNOSE).

2. *TSCA section 8(a) small manufacturers definition update.* The TSCA section 8(a) small manufacturer definition update proposed definition is as follows:

- First standard, A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any) are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer (including importer) is greater than 100,000 pounds, the manufacturer or importer will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under the second standard of this definition.
- Second Standard. A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

Under the proposed definition, the only change from the current TSCA section 8(a) small manufacturer definition is to increase levels for revenue size standards. As a result, EPA expects that no currently exempt small manufacturers would become newly subject to any current TSCA section 8(a) rules under this proposed definition, because all manufacturers that are currently exempt would remain exempt under this proposal. Moreover, the proposed rule would allow exemptions for certain current reporters, thereby eliminating their reporting burden. However, a small amount of incremental burden is incurred for rule familiarization.

As done for the CDR revisions portion of the proposed rule, EPA analyzed potential small business impacts for purposes of the small entity analysis using the SBA size standards which are either revenue or employment based, depending on the industry sector. For the small manufacturer definition update, EPA estimates that 732 small parent entities would potentially be affected by the proposed rule. Based on estimated compliance costs annualized over a 10-year period and average

revenue data for parent entities, EPA estimates that the cost-to-sales ratio of the small manufacturer definition update portion of the proposed rule would be less than 1% for all of these small parent entities (100 percent) (Ref. 5). Per EPA guidance, if impacts are less than 1%, a certification that the rule will not result in a significant (economic) impact on a substantial number of small entities can be made no matter the number of small entities affected. Therefore, the Agency concludes that the small manufacturer definition update portion of the proposed rule would not affect a significant number of small entities (no SISNOSE). Also note that there are no adverse small entity impacts to small government entities because under the post-change conditions all entities defined as small for purposes of small government assessment are the same entities that are newly eligible to take the small government exemption and eliminate their CDR reporting burden entirely.

3. *CDR rule overall.* Note that the two EAs' analyses cover overlapping groups, from which results from each analysis can be synthesized to reach an overall conclusion that the overall compliance costs associated with the proposed rule would not have a significant impact on a substantial number of small entities (overall no SISNOSE).

EPA continues to be interested in the potential impacts of this proposed rule on small entities and welcomes comments on issues related to such impacts.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and would not significantly or uniquely affect small governments. According to the information derived using the 2016 CDR, there are government entities that report to CDR, including: seven municipalities, one county-level public utility district, and one tribal entity. However, under the proposed changes, four of the municipalities would be exempt, with the remaining entities incurring a minimal average incremental burden and cost per site at about 3 hours and $262 per year, respectively. Consequently, impacts would not exceed $100 million for all governments. Additionally, under the proposed small government definition, four government entities would be exempt from TSCA section 8(a) reporting requirements (Ref. 5).

In sum, the proposed rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA.

F. Executive Order 13132: Federalism

This action would not have federalism implications. It would 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 as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action would not have tribal implications because it is not expected to have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). According to the information presented in the economic analysis for the TSCA section 8(a) small manufacturer definition update (Ref. 5), there is one tribal entity that reported during the 2016 CDR collection. Under the proposed rule, this entity is estimated to incur a minimal average incremental burden and cost per site at about 1 hour and $103 per year, respectively. Consequently, EPA has concluded that the impacts of the proposed rule would not significantly nor uniquely affect the communities of tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997), requires that federal agencies examine the impacts of each regulatory action on children for any economically significant regulation (as defined by Executive Order 12866) that the Agency has reason to believe may disproportionately affect children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it would not establish an environmental standard intended to mitigate health or safety risks. Nevertheless, the information obtained by the reporting required by this proposed rule would be used to inform the Agency's decision-making process regarding chemical substances to which children may be disproportionately exposed. This information would also assist the Agency and others in determining whether the chemical substances covered in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

Because this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The Agency believes that the rule would improve the information collected under CDR and better assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by the CDR. Because the CDR is an information collection requirement, the information that would be improved through the proposed rule would enable the Agency to target educational, regulatory, or enforcement activities towards industries or chemical substances that pose the greatest risks and/or to target programs for geographic areas that are at the highest risk. Thus, the information to be gathered under the proposed rule would help EPA make decisions that would benefit potentially at-risk communities, some of which may be disadvantaged.

The proposed rule is directed at manufacturers (including importers) of chemical substances. All consumers of these chemical products and all workers who come into contact with these chemical substances could benefit if data regarding the chemical substances' health and environmental effects were developed. Therefore, it would not appear that the costs and the benefits of the proposed rule would be disproportionately distributed across different geographic regions or among different categories of individuals.

List of Subjects

40 CFR Part 704

Environmental protection, Toxic substances control act, Reporting and recordkeeping requirements.

40 CFR Part 711

Environmental protection, Toxic substances control act, TSCA chemical data reporting and recordkeeping requirements.

40 CFR Part 712

Environmental protection, Toxic substances control act, Chemical information rules.

Dated: April 12, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, EPA proposes to amend 40 CFR parts 704, 711 and 712 as follows:

PART 704—[AMENDED]

■ 1. The authority citation for part 704 to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Section 704.3 is amended by:
■ a. Revising the definition of ''small manufacturer or importer''.
■ b. Adding in alphabetical order the definition for ''small government''.

The additions and revisions read as follows:

§ 704.3 Definitions.

* * * * *

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

* * * * *

Small manufacturer means a manufacturer (including importer) that meets either of the following standards:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $110 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies as small under standard (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $11million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

(3) *Inflation index.* EPA will make use of the Gross Domestic Product deflators, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Gross Domestic Product deflator has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later. EPA will provide notification in the **Federal Register** when changing the total annual sales values.

* * * * *

■ 3. Section 704.104 is amended by revising paragraph (c)(2) to read as follows:

§ 704.104 Hexafluoropropylene oxide.

* * * * *

(c) * * *

(2) Persons described in § 704.5 (a) through (f).

* * * * *

PART 711—[AMENDED]

■ 4. The authority citation for part 711 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 5. Section 711.1 is amended by revising paragraph (a) and (c) to read as follows:

§ 711.1 Scope and compliance.

(a) This part specifies reporting and recordkeeping procedures under section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(a)) for certain manufacturers (including importers) of chemical substances. TSCA section 8(a) authorizes the EPA Administrator to require reporting of information necessary for the administration of TSCA.

* * * * *

(c) TSCA section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. Section 16 of TSCA provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8(a) information and to otherwise restrain any violation of TSCA section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.) TSCA section 11 allows for inspections to assure compliance and the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary.

* * * * *

■ 6. In section 711.3:
■ a. Revise the definition for *e-CDRweb;*
■ b. Revise the definition for *Manufacture;*
■ c. Revise paragraph (1) of the definition for *Site;*
■ d. Remove the definition for *U.S. parent company.*
■ e. Add alphabetically the definitions for *Inorganic chemical substance* and *Parent company.*

The additions and revisions read as follows:

§ 711.3 Definitions.

* * * * *

e-CDRweb means the electronic, web-based tool provided by EPA for the completion of Form U and submission of the CDR data.

* * * * *

Inorganic chemical substance means any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups.

* * * * *

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. A chemical substance is co-

manufactured by the person who physically does the manufacturing and the person contracting for such production when that chemical substance, manufactured other than by import, is:

(1) Produced exclusively for another person who contracts for such production, and

(2) That other person dictates the specific chemical identity of the chemical substance and controls the total amount produced and the basic technology for the manufacturing process.

* * * * *

Parent company means the highest-level company(s) of the site's ownership hierarchy as of the start of the submission period during which data are being reported according to the following instructions. The U.S. parent company is located within the United States while the foreign parent company is located outside the United States:

(1) If the site is entirely owned by a single U.S. company that is not owned by another company, that single company is the U.S. parent company.

(2) If the site is entirely owned by a single U.S. company that is, itself, owned by another U.S.-based company (*e.g.,* it is a division or subsidiary of a higher-level company), the highest-level company in the ownership hierarchy is the United States parent company. If there is a higher-level parent company that is outside of the United States, the highest-level foreign company in the ownership hierarchy is the foreign parent company.

(3) If the site is owned by more than one company (*e.g.,* company A owns 40 percent, company B owns 35 percent, and company C owns 25 percent), the highest-level U.S. company with the largest ownership interest in the site is the U.S. parent company. If there is a higher-level foreign company in the ownership hierarchy, that company is the foreign parent company.

(4) If the site is owned by a 50:50 joint venture or a cooperative, the joint venture or cooperative is its own parent company. If the site is owned by a U.S. joint venture or cooperative, the highest level of the joint venture or cooperative is the U.S. parent company. If the site is owned by a joint venture or cooperative outside the United States, the highest level of the joint venture or cooperative outside the United States is the foreign parent company.

(5) If the site is entirely owned by a foreign company (*i.e.,* without a U.S.-based subsidiary within the site's ownership hierarchy), the highest-level foreign parent company is the facility's foreign parent company.

(6) If the site is federally owned, the highest-level federal agency or department is the U.S. parent company.

(7) If the site is owned by a non-federal public entity, that entity (such as a municipality, State, or tribe) is the U.S. parent company.

* * * * *

Sites * * *

(1) For chemical substances manufactured under contract, *i.e.,* by a co-manufacturer, the site is the location where the chemical substance is physically manufactured.

* * * * *

■ 7. Section 711.6 is amended by revising the section heading, the introduction paragraph and the first sentence in paragraph (a)(4) to read as follows.

§ 711.6 Chemical substances for which information is not required.

The following groups or categories of chemical substances are exempted from some or all of the reporting requirements of this part, with the following exception: A chemical substance described in paragraph (a)(1), (a)(2), or (a)(4), or (b) of this section is not exempted from any of the reporting requirements of this part if that chemical substance is the subject of a rule proposed or promulgated under TSCA sections 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA sections 4, 5(e), or 5(f), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

* * * * *

(a) * * *

(4). *Water and certain forms of natural gas.*

* * * * *

■ 8. Section 711.8 is amended by revising paragraph (a) and (b) to read as follows:

§ 711.8 Persons who must report.

* * * * *

(a) *Persons subject to recurring reporting*—Any person who manufactured (including imported) for commercial purposes 25,000 lb (11,340 kg) or more of a chemical substance described in § 711.5 at any single site owned or controlled by that person during any calendar year since the last principal reporting year.

* * * * *

(b) *Exceptions.* Any person who manufactured (including imported) for commercial purposes any chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4), or 6, or is the subject of an order in effect under TSCA sections 4, 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7 is subject to reporting as described in § 711.8(a), except that the applicable production volume threshold is 2,500 lb (1,134 kg).

■ 9. Section 711.9 is revised to read as follows:

§ 711.9 Persons not subject to this part.

A person described in § 711.8 is not subject to the requirements of this part if that person qualifies as a small manufacturer or small government as those terms are defined in 40 CFR 704.3. Notwithstanding this exclusion, a person who qualifies as a small manufacturer or small government is subject to this part with respect to any chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, or is the subject of an order in effect under TSCA sections 4 or 5(e), or is the subject of relief that has been granted under a civil action under TSCA sections 5 or 7.

■ 10. Section 711.10 is revised to read as follows:

§ 711.10 Activities for which reporting is not required.

A person described in § 711.8 is not subject to the requirements of this part with respect to any chemical substance described in § 711.5, when:

(a) The person manufactured or imported the chemical substance solely in small quantities for research and development.

(b) The person imported the chemical substance as part of an article.

(c) The person manufactured the chemical substance in any of the following manners:

(1) Any byproduct if its only commercial purpose is for use by public or private organizations that (i) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)

(2) Byproduct substances listed in subparagraph (i) for the following manufacturing processes, when recycled or otherwise used within a site-limited, physically enclosed system that is part of the same overall manufacturing process from which the byproduct substance was generated, and when the site is reporting the byproduct or a different chemical substance that was manufactured from the recycled

byproduct or manufactured in the same overall manufacturing process:

(i) *List of processes and related byproduct substances.*

(A) Portland Cement Manufacturing (*i.e.,* CASRN 68475–76–3, Flue dust, portland cement).

(B) Kraft Pulping Process (*i.e.,* CASRN 66071–92–9, Sulfite liquors and Cooking liquors, spent; and CASRN 471–34–1, Carbonic acid calcium salt (1:1)).

(ii) *Amendments.* EPA may amend the exemptions list in paragraph (c)(2)(i) of this section on its own initiative or in response to a request from the public based on EPA's determination of whether the byproduct substance and process described meet the criteria explained in paragraph (c)(2) of this section, based on the considerations listed in paragraph (c)(2)(ii)(B) of this section.

(A) Any person may request that EPA amend the chemical substance list in paragraph (c)(2)(i) of this section. Your request must be in writing and must be submitted to the address provided in 40 CFR 700.17(a). Please label your request as follows: Attention: TSCA Chemical Data Reporting—Byproduct Exemption Request. Requests must identify the manufacturing process and byproduct chemical substance in question, as well as its CASRN or other chemical identification number as identified in § 711.15(b)(3)(i), and must contain a written rationale for the request that provides sufficient specific information, addressing the considerations listed in (c)(2)(ii)(B) of this section, including cites and relevant documents, to demonstrate to EPA that the byproduct substance and process in question either does or does not meet the criteria explained in paragraph (c)(2) of this section. If a request related to a particular byproduct substance and process is resubmitted, any subsequent request must clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request. EPA will issue a written response to each request within 120 days of receipt of the request and will maintain copies of these responses in a docket that will be established for each reporting cycle.

(B) *Considerations.* In making its determination of whether this exemption should apply to a particular manufacturing process and related byproduct substance, EPA will consider the totality of information available for the process and related byproduct substance in question, including but not limited to, one or more of the following considerations:

(*1*) Whether the byproduct substance is recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured.

(*2*) Whether the site is reporting under CDR other chemical substances, in particular a chemical substance other than the byproduct substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process.

(*3*) Whether EPA has a current interest in the byproduct substance.

(*4*) That the byproduct substance must have already been reported under CDR or would be expected to be reported if not exempted by this exemption.

(C) As needed, the Agency will initiate rulemaking to make revisions to the list of substances in paragraph (c)(2)(i) of this section.

(D) To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, requests must be submitted to EPA no later than 12 months prior to the start of the next principal reporting year.

(3) A quantity of the byproduct that is manufactured solely in the following equipment when it is not integral to the chemical manufacturing processes of the site:

(i) Pollution control equipment.

(ii) Boilers used to generate heat or electricity for that site.

(4) The chemical substances described in this section: (Although they are manufactured for commercial purposes under TSCA, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(i) Any impurity.

(ii) Any byproduct which is not used for commercial purposes.

(iii) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(iv) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(v) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(vi) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(vii) Any chemical substance which results from a chemical reaction that occurs when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(viii) Any nonisolated intermediate.

■ 11. Section 711.15 is revised to read as follows.

§ 711.15 Reporting information to EPA.

Any person who must report under this part, as described in § 711.8, must submit the information described in this section for each chemical substance described in § 711.5 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year (*e.g.,* for the 2020 submission period, consider calendar years 2016, 2017, 2018, and 2019, because 2015 was the last principal reporting year). The principal reporting year for each submission period is the previous calendar year (*e.g.,* the principal reporting year for the 2020 submission period is calendar year 2019). For all submission periods, a separate report must be submitted for each chemical substance at each site for which the submitter is required to report. A submitter of information under

this part must report information as described in this section to the extent that such information is known to or reasonably ascertainable by that person.

(a) *Reporting information to EPA.* Any person who reports information to EPA must complete a Form U using the e-CDRweb reporting tool provided by EPA at the address set forth in § 711.35. The submission must include all information described in paragraph (b) of this section. Persons must submit the chemical reports on a separate single Form U for each site for which the person is required to report. The e-CDRweb reporting tool is described in the instructions available from EPA at the website set forth in § 711.35.

(b) *Information to be reported.* The information described in paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section must be reported for each chemical substance manufactured (including imported) in an amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year. The requirement to report information described in paragraph (b)(4) of this section is subject to exemption as described in § 711.6. Persons that elect to report eligible chemical substances in categories must report as described in § 711.15(b)(3)(i).

(1) *A certification statement signed and dated by an authorized official of the submitter company.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person's name, official title, and email address.

(2) *Company and site information.* The following currently correct company and site information must be reported for each site at which a reportable chemical substance is manufactured (including imported) above the applicable production volume threshold, as described in this section (see § 711.3 for the ''site'' for importers and special situations).

(i) The legal name, address, and Dun and Bradstreet D–U–N–S® (D&B) number for the highest-level parent company located in the United States and, if one exists, the highest-level foreign-based parent company. A submitter under this part must obtain a D&B number for the parent company if none exists and must report using the standardized conventions for the naming of a parent company as provided in the CDR Instructions for Reporting identified in § 711.35.

(ii) The name of a person who will serve as technical contact for the submitter company who will be able to answer questions about the information submitted by the company to EPA, and that technical contact person's full mailing address, telephone number, and email address.

(iii) The legal name and full street address of each site. A submitter under this part must include the appropriate D&B number for each site reported, and the county or parish (or other jurisdictional indicator) in which the site is located. A submitter under this part must obtain a D&B number for the site reported if none exists. For a co-manufacturing situation, the contracting company must report both the site controlling the contract and the producing company's site information.

(iv) The six-digit NAICS code for the site. A submitter under this part must include the appropriate six-digit NAICS code for each site reported.

(3) *Chemical-specific information.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in paragraph (b) of this section:

(i) The specific, currently correct CA Index name as used to list the chemical substance on the TSCA Inventory and the correct corresponding CASRN for each reportable chemical substance at each site. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using the corresponding TSCA Accession Number that is listed on the public portion of the Inventory. In addition to reporting the chemical identifying number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 3 of this paragraph.

(A) *Alternative reporting for some inorganic byproduct chemical substances.* Alternately, a submitter under this part may report an inorganic byproduct chemical substance using a designated metal compound category, unless the chemical substance is excluded from reporting in categories. Metal compound categories are listed in Table 4 of this paragraph. For purposes of determining whether any of the thresholds specified in § 711.8 are met for a metal compound category, a submitter must make the threshold determination based on the total amount of all members of the metal compound category manufactured at the site.

Excluded substances. Substances excluded from reporting in categories include barium carbonate (CASRN 513–77–9); chemical substances subject to the rules, orders, or other TSCA actions described in § 711.6; and chemicals undergoing risk evaluation under TSCA section 6, as described on EPA's CDR website at *https://www.epa.gov/cdr.*

TABLE 3—CODES TO SPECIFY TYPE OF CHEMICAL IDENTIFYING NUMBER

Code	Number type
A	TSCA Accession Number.
C	Chemical Abstracts Service Registry Number (CASRN).
M	TSCA Metal Compound Category Code.

TABLE 4—METAL COMPOUND CATEGORIES FOR INORGANIC BYPRODUCT CHEMICAL SUBSTANCES ONLY

Code	Category name
M01	Antimony and Antimony Compounds: Includes any unique chemical substance that contains antimony as part of that chemical's structure.
M02	Arsenic and Arsenic Compounds: Includes any unique chemical substance that contains arsenic as part of that chemical's structure.
M03	Barium and Barium Compounds: Includes any unique chemical substance that contains barium as part of that chemical's structure.
M04	Beryllium and Beryllium Compounds: Includes any unique chemical substance that contains beryllium as part of that chemical's structure.
M05	Cadmium and Cadmium Compounds: Includes any unique chemical substance that contains cadmium as part of that chemical's structure.
M06	Chromium and Chromium Compounds: Includes any unique chemical substance that contains chromium as part of that chemical's structure.
M07	Cobalt and Cobalt Compounds: Includes any unique chemical substance that contains cobalt as part of that chemical's structure.
M08	Copper and Copper Compounds: Includes any unique chemical substance that contains copper as part of that chemical's structure.
M09	Lead and Lead Compounds: Includes any unique chemical substance that contains lead as part of that chemical's structure.
M10	Manganese and Manganese Compounds: Includes any unique chemical substance that contains manganese as part of that chemical's structure.
M11	Mercury and Mercury Compounds: Includes any unique chemical substance that contains mercury as part of that chemical's structure.
M12	Molybdenum and Molybdenum compounds: Includes any unique chemical substance that contains molybdenum as part of that chemical's structure.
M13	Nickel and Nickel Compounds: Includes any unique chemical substance that contains nickel as part of that chemical's structure.

TABLE 4—METAL COMPOUND CATEGORIES FOR INORGANIC BYPRODUCT CHEMICAL SUBSTANCES ONLY—Continued

Code	Category name
M14	Selenium and Selenium Compounds: Includes any unique chemical substance that contains selenium as part of that chemical's structure.
M15	Silver and Silver Compounds: Includes any unique chemical substance that contains silver as part of that chemical's structure.
M16	Thallium and Thallium Compounds: Includes any unique chemical substance that contains thallium as part of that chemical's structure.
M17	Vanadium and Vanadium compounds: Includes any unique chemical substance that contains vanadium as part of that chemical's structure.
M18	Zinc and Zinc Compounds: Includes any unique chemical substance that contains zinc as part of that chemical's structure.

(B) *Joint submissions. (1)* If an importer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must use e-CDRweb to ask the supplier to provide the correct chemical identity and, in the case of a mixture, chemical function information directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically, using e-CDRweb and CDX (see § 711.35), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission.

(*2*) If a manufacturer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because the reportable chemical substance is manufactured using a reactant having a specific chemical identity that is unknown to the manufacturer and claimed as confidential by its supplier, the manufacturer must use e-CDRweb to ask the supplier of the confidential reactant to provide the correct chemical identity of the confidential reactant directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically using e-CDRweb and CDX (see § 711.35), and for clearly referencing the manufacturer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance, and a copy of the request to the supplier must be included with the importer's submission.

(*3*) EPA will only accept joint submissions that are submitted electronically using e-CDRweb and CDX (see § 711.35) and that clearly reference the primary submission to which they refer.

(ii) For the principal reporting year only, a statement indicating, for each reportable chemical substance at each site, whether the chemical substance is manufactured in the United States, imported into the United States, or both manufactured in the United States and imported into the United States.

(iii) For the principal reporting year, the total annual volume (in pounds) of each reportable chemical substance domestically manufactured or imported at each site. The total annual domestically manufactured volume (not including imported volume) and the total annual imported volume must be separately reported. These amounts must be reported to two significant figures of accuracy. In addition, the total annual volume (domestically manufactured plus imported volumes in pounds) of each reportable chemical substance at each site for each complete calendar year since the last principal reporting year.

(iv) For the principal reporting year only, the volume used on site and the volume directly exported of each reportable chemical substance domestically manufactured or imported at each site. These amounts must be reported to two significant figures of accuracy.

(v) For the principal reporting year only, a designation indicating, for each imported reportable chemical substance at each site, whether the imported chemical substance is physically present at the reporting site.

(vi) For the principal reporting year only, the percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance, for each reportable chemical substance at each site, that is manufactured as a byproduct at the site. Where this percentage accounts for less than 5 percent of the total production volume of the reportable chemical substance, submitters instead must report the percentage, rounded off to the closest 1 percent.

(vii) For the principal reporting year only, a designation indicating, for each reportable chemical substance at each site, whether the chemical substance is being recycled or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream.

(viii) For the principal reporting year only, the total number of workers reasonably likely to be exposed to each reportable chemical substance at each site. For each reportable chemical substance at each site, the submitter must select from among the ranges of workers listed in Table 5 of this paragraph and report the corresponding code (*i.e.,* W1 through W8):

TABLE 5—CODES FOR REPORTING NUMBER OF WORKERS REASONABLY LIKELY TO BE EXPOSED

Code	Range
W1	Fewer than 10 workers.
W2	At least 10 but fewer than 25 workers.
W3	At least 25 but fewer than 50 workers.
W4	At least 50 but fewer than 100 workers.
W5	At least 100 but fewer than 500 workers.
W6	At least 500 but fewer than 1,000 workers.
W7	At least 1,000 but fewer than 10,000 workers.
W8	At least 10,000 workers.

(ix) For the principal reporting year only, the maximum concentration, measured by percentage of weight, of each reportable chemical substance at the time it is sent off-site from each site. If the chemical substance is site-limited, you must report the maximum concentration, measured by percentage of weight of the reportable chemical substance at the time it is reacted on-site to produce a different chemical substance. This information must be reported regardless of the physical form(s) in which the chemical substance is sent off-site/reacted on-site. For each chemical substance at each site, select the maximum concentration of the chemical substance from among the ranges listed in Table 6 of this paragraph and report the corresponding code (*i.e.,* M1 through M5):

TABLE 6—CODES FOR REPORTING MAXIMUM CONCENTRATION OF CHEMICAL SUBSTANCE

Code	Concentration range (percent weight)
M1	Less than 1 percent by weight.
M2	At least 1 but less than 30 percent by weight.
M3	At least 30 but less than 60 percent by weight.
M4	At least 60 but less than 90 percent by weight.
M5	At least 90 percent by weight.

(x) For the principal reporting year only, the physical form(s) of the reportable chemical substance as it is sent off-site from each site. If the chemical substance is site-limited, you must report the physical form(s) of the reportable chemical substance at the time it is reacted on-site to produce a

different chemical substance. For each chemical substance at each site, the submitter must report as many physical forms as applicable from among the physical forms listed in this unit:

(A) Dry powder.
(B) Pellets or large crystals.
(C) Water- or solvent-wet solid.
(D) Other solid.
(E) Gas or vapor.
(F) Liquid.

(xi) For the principal reporting year only, submitters must report the percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance, reported in response to paragraph (b)(3)(iv) of this section, that is associated with each physical form reported under paragraph (b)(3)(x) of this section.

(4) *Chemical-specific information related to processing and use.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in this section. Persons subject to paragraph (b)(4) of this section must report the information described in paragraphs (b)(4)(i) and (b)(4)(ii) of this section for each reportable chemical substance at sites under their control and at sites that receive a reportable chemical substance from the submitter directly or indirectly (including through a broker/distributor, from a customer of the submitter, *etc.*). Information reported in response to this paragraph must be reported for the principal reporting year only and only to the extent that it is known to or reasonably ascertainable by the submitter. Information required to be reported under this paragraph is limited to domestic (*i.e.,* within the customs territory of the United States) processing and use activities. If information responsive to a given data requirement under this paragraph, including information in the form of an estimate, is not known or reasonably ascertainable, the submitter is not required to respond to the requirement.

(i) *Industrial processing and use information*—(A) A designation indicating the type of industrial processing or use operation(s) at each site that receives a reportable chemical substance from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not). For each chemical substance, report the letters which correspond to the appropriate processing or use operation(s) listed in Table 7 of this paragraph. A particular designation may need to be reported more than once, to the extent that a submitter reports more than one sector (under paragraph (b)(4)(i)(B) of this section) that applies to a given designation under this paragraph.

TABLE 7—CODES FOR REPORTING TYPE OF INDUSTRIAL PROCESSING OR USE OPERATION

Designation	Operation
PC	Processing as a reactant.
PF	Processing—incorporation into formulation, mixture, or reaction product.
PA	Processing—incorporation into article.
PK	Processing—repackaging.
U	Use—non-incorporative activities.

(B) A code indicating the sector(s) that best describe the industrial activities associated with each industrial processing or use operation reported under paragraph (b)(4)(i)(A) of this section. For each chemical substance, report the code that corresponds to the appropriate sector(s) listed in Table 8 of this paragraph. A particular sector code may need to be reported more than once, to the extent that a submitter reports more than one function code (under paragraph (b)(4)(i)(C) of this section) that applies to a given sector code under this paragraph.

TABLE 8—CODES FOR REPORTING INDUSTRIAL SECTORS

Code	Sector description
IS1	Agriculture, forestry, fishing, and hunting.
IS2	Oil and gas drilling, extraction, and support activities.
IS3	Mining (except oil and gas) and support activities.
IS4	Utilities.
IS5	Construction.
IS6	Food, beverage, and tobacco product manufacturing.
IS7	Textiles, apparel, and leather manufacturing.
IS8	Wood product manufacturing.
IS9	Paper manufacturing.
IS10	Printing and related support activities.
IS11	Petroleum refineries.
IS12	Asphalt paving, roofing, and coating materials manufacturing.
IS13	Petroleum lubricating oil and grease manufacturing.
IS14	All other petroleum and coal products manufacturing.
IS15	Petrochemical manufacturing.
IS16	Industrial gas manufacturing.
IS17	Synthetic dye and pigment manufacturing.
IS18	Carbon black manufacturing.
IS19	All other basic inorganic chemical manufacturing.
IS20	Cyclic crude and intermediate manufacturing.
IS21	All other basic organic chemical manufacturing.
IS22	Plastics material and resin manufacturing.
IS23	Synthetic rubber manufacturing.
IS24	Organic fiber manufacturing.
IS25	Pesticide, fertilizer, and other agricultural chemical manufacturing.
IS26	Pharmaceutical and medicine manufacturing.
IS27	Paint and coating manufacturing.
IS28	Adhesive manufacturing.
IS29	Soap, cleaning compound, and toilet preparation manufacturing.
IS30	Printing ink manufacturing.
IS31	Explosives manufacturing.
IS32	Custom compounding of purchased resins.
IS33	Photographic film, paper, plate, and chemical manufacturing.
IS34	All other chemical product and preparation manufacturing.
IS35	Plastics product manufacturing.
IS36	Rubber product manufacturing.
IS37	Non-metallic mineral product manufacturing (includes cement, clay, concrete, glass, gypsum, lime, and other non-metallic mineral product manufacturing).
IS38	Primary metal manufacturing.
IS39	Fabricated metal product manufacturing.
IS40	Machinery manufacturing.
IS41	Computer and electronic product manufacturing.
IS42	Electrical equipment, appliance, and component manufacturing.
IS43	Transportation equipment manufacturing.
IS44	Furniture and related product manufacturing.
IS45	Miscellaneous manufacturing.
IS46	Wholesale and retail trade.
IS47	Services.
IS48	Other (requires additional information).

(C) For each sector reported under paragraph (b)(4)(i)(B) of this section, function category code(s) as provided in the CDR Instructions for Reporting identified in § 711.35 must be selected to designate the function category(ies) that best represents the specific manner in which the chemical substance is used. A particular function category may need to be reported more than once, to the extent that a submitter reports more than one industrial processing or use operation/sector combination (under paragraphs (b)(4)(i)(A) and (b)(4)(i)(B) of this section) that applies to a given function category under this paragraph. If more than 10 unique combinations of industrial processing or use operations/sector/function categories apply to a chemical substance, submitters need only report the 10 unique combinations for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical substance, measured by weight. If none of the listed function categories accurately describes a use of a chemical substance, the category ''Other'' may be used, and must include a description of the use.

(D) The estimated percentage, rounded off to the closest 10 percent, of total production volume of the reportable chemical substance associated with each combination of industrial processing or use operation, sector, and function category. Where a

particular combination of industrial processing or use operation, sector, and function category accounts for less than 5 percent of the submitter's site's total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent if the production volume attributable to that industrial processing or use operation, sector, and function category combination is 25,000 lb (11,340 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, sector, and function category.

(E) For each combination of industrial processing or use operation, sector, and function category, the submitter must estimate the number of sites at which each reportable chemical substance is processed or used. For each combination associated with each chemical substance, the submitter must select from among the ranges of sites listed in Table 9 of this paragraph and report the corresponding code (*i.e.,* S1 through S7):

TABLE 9—CODES FOR REPORTING NUMBERS OF SITES

Code	Range
S1	Fewer than 10 sites.
S2	At least 10 but fewer than 25 sites.
S3	At least 25 but fewer than 100 sites.
S4	At least 100 but fewer than 250 sites.
S5	At least 250 but fewer than 1,000 sites.
S6	At least 1,000 but fewer than 10,000 sites.
S7	At least 10,000 sites.

(F) For each combination of industrial processing or use operation, sector, and function category, the submitter must estimate the number of workers reasonably likely to be exposed to each reportable chemical substance. For each combination associated with each chemical substance, the submitter must select from among the worker ranges listed in paragraph (b)(3)(viii) of this section and report the corresponding code (*i.e.,* W1 though W8).

(ii) *Consumer and commercial use information*—(A) Using the codes as provided in the CDR Instructions for Reporting identified in § 711.35, submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial products in which each reportable chemical substance is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10 codes apply to a chemical substance, submitters need only report the 10 codes for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight. If none of the listed consumer and commercial product categories accurately describes the consumer and commercial products in which each reportable chemical substance is used, the category ''Other'' may be used, and must include a description of the use.

(B) for each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, code(s) described in paragraph (b)(4)(i)(C) of this section must be selected to designate the function category(ies) that best represents the specific manner in which the chemical substance is used. A particular function category may need to be reported more than once, to the extent that a submitter reports more than one consumer or commercial product category (under paragraphs (b)(4)(ii)(A) of this section) that applies to a given function category under this paragraph. If none of the listed function categories accurately describes a use of a chemical substance, the category ''Other'' may be used, and must include a description of the use.

(C) An indication, within each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, whether the use is a consumer or a commercial use.

(D) Submitters must determine, within each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, whether any amount of each reportable chemical substance manufactured (including imported) by the submitter is present in (for example, a plasticizer chemical substance used to make pacifiers) or on (for example, as a component in the paint on a toy) any consumer products intended for use by children age 14 or younger, regardless of the concentration of the chemical substance remaining in or on the product. Submitters must select from the following options: The chemical substance is used in or on any consumer products intended for use by children, the chemical substance is not used in or on any consumer products intended for use by children, or information as to whether the chemical substance is used in or on any consumer products intended for use by children is not known to or reasonably ascertainable by the submitter.

(E) The estimated percentage, rounded off to the closest 10 percent, of the submitter's site's total production volume of the reportable chemical substance associated with each consumer and commercial product category. Where a particular consumer and commercial product category accounts for less than 5 percent of the total production volume of a reportable chemical substance, the percentage must not be rounded off to 0 percent if the production volume attributable to that commercial and consumer product category is 25,000 lb (11,340 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1 percent, of the submitter's site's total production volume of the reportable chemical substance associated with the particular consumer and commercial product category.

(F) Where the reportable chemical substance is used in consumer or commercial products, the estimated typical maximum concentration, measured by weight, of the chemical substance in each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section. For each chemical substance in each commercial and consumer product category reported under paragraph (b)(4)(ii)(A) of this section, submitters must select from among the ranges of concentrations listed in Table 6 in paragraph (b)(3)(ix) of this section and report the corresponding code (*i.e.,* M1 through M5).

(G) Where the reportable chemical substance is used in a commercial product, the submitter must estimate the number of commercial workers reasonably likely to be exposed to each reportable chemical substance. For each combination associated with each substance, the submitter must select from among the worker ranges listed in Table 5 in paragraph (b)(3)(viii) of this section and report the corresponding code (*i.e.,* W1 though W8).

■ 12. Section 711.20 is revised to read as follows:

§ 711.20 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during an applicable submission period, which runs from June 1 to September 30 at 4-year intervals, beginning in 2020. In each submission period, any person described in § 711.8 must report as described in this part.

■ 13. Section 711.22 is amended by revising paragraph (c) to read as follows:

§ 711.22 Duplicative reporting.

* * * * *

(c) *Co-manufactured chemicals.* This part requires that only one report per site be submitted on each chemical substance described in § 711.5. When a company contracts with a producing company to manufacture a chemical substance, and each party meets the definition of ''manufacturer'' as set forth in § 711.3, the contracting company must initiate the required report for that site as the primary submitter. The contracting company must indicate on the report that this is a co-manufacturing situation, notify the producing company, and record the production volume domestically co-manufactured as set forth in § 711.15(b)(3) and processing and use information set forth in § 711.15(b)(4). Upon notification by the contracting company, the producing company must also record the production volume domestically co-manufactured and complete the rest of the report as prompted by e-CDRweb.

* * * * *

■ 14. Section 711.30 is revised to read as follows.

§ 711.30 Confidentiality claims.

(a) Generally. (1) Any person submitting information under this part may assert a confidentiality claim for that information at the time it is submitted, except for information described in paragraph (2).

Any such confidentiality claims must be asserted at the time the information is submitted. These claims will apply only to the information submitted with the claim. Instructions for asserting confidentiality claims are provided in the document identified in § 711.35. Information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2.

(2) *Exceptions.* Confidentiality claims cannot be made:

(i) For public contact information if voluntarily provided;

(ii) For chemical identities listed on the public portion of the TSCA Inventory or for chemical category identification when reporting pursuant to § 711.15(b)(3)(i);

(iii) For processing and use data elements required by § 711.15(b)(4)(i)(A), (B), and (C) and § 711.15(b)(4)(ii)(A), (B), and (C), or

(iv) When a response is left blank or designated as not known or reasonably ascertainable.

(3) All confidentiality claims must be substantiated at time of submission, in accordance with the requirements in subsections (b) through (f) of this section. Confidentiality claims for the following data elements are exempt from this substantiation requirement:

(i) Production volume information required pursuant to § 711.15(b)(3)(iii).

(ii) Joint submission information from the primary submitter including trade name and supplier identification required pursuant to § 711.15(b)(3)(i)(A), (B), and (C).

(iii) Joint submission information from the secondary submitter including the percentage of formulation required pursuant to § 711.15(b)(3)(i)(A), (B), and (C).

(4) All confidentiality claims require certification in accordance with subsection (g) of this section. All asserted confidentiality claims, whether subject to substantiation and review or not, may only be asserted consistent with the representations set forth in the certification described in subsection (h) of this section.

(b) *All confidentiality claims requiring substantiation at time of submission.* For each data element claimed as confidential, you must submit with your report detailed written answers to the following questions signed and dated by an authorized official.

(1) Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, explain the substantial harm.

(2) To the extent your business has disclosed the information to others (both internally and externally), has your business taken precautions to protect the disclosed information? If yes, please explain and identify the specific measures or internal controls your business has taken to protect the information claimed as confidential.

(3) Does any of the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publications, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.

(4) Does any of the information you are claiming as confidential constitute a trade secret?

(5) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If so, indicate the number of years (between 1–10 years) or the specific date after which the claim is withdrawn.

(6) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(c) *Additional requirements for specific chemical identity.* The specific chemical identity includes the CA Index name and corresponding CASRN as described in § 711.15(b)(3) of this part, and does not include generic chemical identities or TSCA Accession Number. Generic chemical identities and accession numbers may not be claimed as confidential. A person may assert a claim of confidentiality for the specific chemical identity of a chemical substance only if the identity of that chemical substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that chemical substance. To assert a claim of confidentiality for the identity of a reportable chemical substance, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions signed and dated by an authorized official.

(1) Is this chemical substance publicly known to be in U.S. commerce by a specific chemical identity or name that is consistent with its listing on the confidential portion of the TSCA Inventory? If yes, explain why the chemical identity should still be afforded confidential status (*i.e.,* the chemical is publicly known only as being distributed in commerce for research and development purposes). If no, complete the certification statement:

> I certify that on the date referenced, I searched the internet for the chemical substance identity (*i.e.,* by both chemical substance name and CASRN). I did not find a reference to this chemical substance which would indicate the chemical is being manufactured or imported for a commercial purpose and is available in the United States by anyone. [provide date].

(2) Does this particular chemical substance leave the site of manufacture (including import) in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(3) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

(4) Would disclosure of the specific chemical name release confidential process information? If yes, please explain?

(d) *Company, site, and technical contact identity information.* A

submitter may assert a claim of confidentiality for a site, company, or technical contact identity only if the linkage of that information to a reportable chemical substance is confidential and not publicly available. To assert a claim of confidentiality to protect the link between the company, site, or technical contact identity and the chemical substance information, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions, as applicable, signed and dated by an authorized official.

(1) Has company, site, or technical contact identity information been linked with a reportable chemical substance in any public document or in any other Federal, State, or local reporting scheme? For example, is the chemical identity linked to a facility in a filing under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 311, namely through a Safety Data Sheet (SDS)? If yes, explain why the information should be treated as confidential.

(e) *Additional requirements for processing and use information.* A submitter may assert a claim of confidentiality for each data element required by § 711.15(b)(4)(i)(D), (E) and (F) and § 711.15(b)(4)(ii)(D), (E) and (F) only if the linkage of the information with a reportable chemical substance is confidential and not publicly available. To assert a claim of confidentiality for each data element required by § 711.15(b)(4) which is potentially eligible for protection from disclosure, you must submit with the report detailed written answers to the questions from paragraph (b) of this section and to the following questions signed and dated by an authorized official:

(1) Is the information claimed as confidential publicly known? For example, is the information available in advertisements or other marketing materials, professional journals or other similar materials, or in non-confidential mandatory or voluntary government filings or publications? Has your company ever publicly released this information? If yes, explain why the information should be treated as confidential.

(2) Has your company ever provided this information on the chemical substance to any person and not asked that it be treated as confidential? If yes, explain why the information should be treated as confidential.

(f) *Joint Submissions.* If a primary submitter asks a secondary submitter to provide information directly to EPA in a joint submission under § 711.15(b)(3)(i)(A) and (B), only the primary submitter may assert a confidentiality claim for the data elements it directly submits to EPA. The primary submitter must substantiate those claims not exempt under subparagraph (a)(3)(ii) of this section. The secondary submitter is responsible for asserting all confidentiality claims for the data elements it submits directly to EPA and substantiating those claims not exempt under subparagraph (a)(3)(iii) of this section.

(g) *Marking substantiations.* If any of the information contained in the answers to the questions listed in subsections (b) though (e) of this section is asserted to contain information that itself is considered to be confidential, you must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(h) *Certification statement for claims.* An authorized official of a person asserting a claim of confidentiality must certify that the submission complies with the requirements of this part by signing and dating the following certification statement:

I certify that all claims for confidentiality asserted with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001. I further certify that: (1) I have taken reasonable measures to protect the confidentiality of the information; (2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and (4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(i) *No claim of confidentiality.* Information not asserted as confidential in accordance with the requirements of this section may be made public without further notice to the submitter.

■ 15. Section 711.35 is amended by revising paragraph (c)(1) to read as follows:

§ 711.35 Electronic filing.

* * * * *

(c) * * *

(1) *By website.* Go to the EPA Chemical Data Reporting internet homepage at *http://www.epa.gov/cdr* and follow the appropriate links.

* * * * *

PART 712—[AMENDED]

■ 16. The authority citation for part 712 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 17. Section 712.25 is amended by revising paragraph (c) to read as follows:

§ 712.25 . Exempt manufacturers and importers.

* * * * *

(c) Persons who qualify as small manufacturers (including importers) in respect to a specific chemical substance listed in § 712.30 are exempt. However, this exemption does not apply with respect to any chemical in § 712.30 designated by an asterisk. A manufacturer is qualified as small and is exempt from submitting a report under this subpart for a chemical substance manufactured at a particular plant site if it meets the definition for small manufacturer in § 704.3.

* * * * *

[FR Doc. 2019–07716 Filed 4–24–19; 8:45 am]

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